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April 25, 2011

Document Control Desk
US Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20852

Re: Varian Medical Systems, Inc. NRC
License No. 45-30957-01, Docket No. 03036666
30-day report – Events 46695 and 46758

Varian Medical Systems, Inc. is submitting the attached Written Notification in accordance with 10 CFR 21.21 (d)(3)(ii) and § 21.21 (d)(4) for Events 46695 and 46758. This is the same event, but has been assigned two event numbers. 46695 was assigned when it was called in for the Part 30 and 46758 was assigned when it was called in for Part 21.

Very truly yours,

Richard G. Piccolo, CHP
Varian Brachytherapy RSO

Copy: Mr. William Dean
Regional Administrator
USNRC Region I
475 Allendale Road
King of Prussia, PA 19406

Ms. Kathy Modes
USNRC Region I
475 Allendale Road
King of Prussia, PA 19406

Att: Tech Tip TT-VS-1247
CTB-VS-640A
Attachment – x-ray and photographs

IEB
RANI

Written notification in accordance with 10 CFR 21.21 (d)(3)(ii) and § 21.21 (d)(4)
Events 46695 and 46758

1. *Name and address of the individual or individuals informing the Commission.*

Richard G. Piccolo
Varian Medical Systems, Inc.
700 Harris Street, Ste. 109
Charlottesville VA 22903

2. *Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.*

VariSource HDR Afterloader – Model VariSource iX

3. *Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.*

The VariSource HDR Afterloader is manufactured by:

Varian Medical Systems, Inc.
Gatwick Road
Crawley, West Sussex RH102RG
United Kingdom

4. *Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.*

The active source wire may jam in the wedge block and cause the source to become stuck outside of the unit's tungsten shield.

This is the first time this event has occurred in a new unit.

The event involving the new unit has occurred only at Grady Memorial Hospital, 80 Jesse Hill Drive SE, Atlanta GA 30303

Engineering evaluation has determined the following:

- a. A very small amount of material was found in a source guide fixture known as the wedge block. The source wire passes through a small bore in this fixture.

- b. The nickel-titanium source wire involved in this incident was manufactured from stock that has been in use for many months.
- c. There have been no known changes to the production workflow that would account for this event.
- d. The integrity of the source wire did not appear compromised in this event. Microscopic examination of the wire did not disclose anything that would have contributed to the wire jam.
- e. The HDR unit properly parked the source in the tungsten safe without the use of the emergency retract handle.
- f. There is a relationship to earlier events involving the wedge block that occurred in late 2008 (Event 44774) though that relationship is not clear beyond the involvement of the wedge block.

Non destructive tests and destructive tests were performed on the wedge block to determine the reason for the jam. These included x-ray imaging and endoscopic examination of the bore of the wedge block. No restriction or defect was identified that would have caused the wire to jam. Images from these studies are attached to this report.

The events that occurred in 2008 were re-visited to determine if there was any connection to the event at Grady, but nothing specific was identified. The earlier events were caused by the accumulation of nickel titanium dust in the bore of the wedge block. A new maintenance protocol has been effective in preventing recurrence of those events and Varian believes that it is an effective solution for those units in the field. Specifically, VariSource units undergo scheduled maintenance wherein the bore of the wedge block is cleaned. In this population of HDR units there have been no wedge block events since the original events occurred.

Root Cause - Varian Medical Systems, Inc. has concluded that the root cause for this event is the bore of the wedge block is not properly designed to tolerate any debris or residue to ensure that the source wire will not become jammed. A new design for the wedge block is being investigated and will be deployed in new production after validation is complete.

The basis for this determination is that a source wire became jammed in the wedge block of a new HDR unit even after the extensive reviews and corrective actions following Event 44774.

Safety hazard – Unintended radiation exposure from the source being outside the tungsten shield. Personnel exposure from this event was a total collective dose equivalent of 2.0 mrem as measured by electronic dosimeter.

5. *The date on which the information of such defect or failure to comply was obtained.*

The event occurred on March 23, 2011. Varian's RSO called the NRC Operations Center on the following day after the source was safely recovered and made a report under 10 CFR 30.50(b)(2). During a subsequent telephone call on Monday April 11, 2011 the NRC advised that a Part 21 filing would be appropriate due to the involvement of the wedge block and initial notification was made by fax to the NRC Operations Center on April 15, 2011.

6. *In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.*

This is the first time a source wire has become jammed in a new unit with a low number of source extensions – likely around 10-15.

Therefore, there are no units similarly affected and we have not seen any similar events with new units in the history of this device.

7. *The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.*

Short term corrective action

Tech Tip TT-VS-1247, which was issued as part of the response to Event 44774 will be applied either during manufacturing or at the time of new unit installation prior to loading the active source wire. A copy of the Tech Tip is attached.

Long term corrective action

A new design for the wedge block is being investigated and will be implemented when finalized. The new wedge block will replace the current design in the production of new VariSource HDR units in Crawley England. After the design is determined it will take several months of testing to ensure it is a valid design change. Varian has a goal of April 30, 2012 for completing this design and its incorporation in new production

units. The target date is dependent on achieving a valid design and may change based on test results.

Varian is considering several design changes. Among them are:

- a. Modify the bore of the wedge block by adding internal structure that would disrupt the way that foreign material behaves. A series of grooves or striations could possibly be cut into the bore. These would break up any foreign material that may be present as the source wire travels through the wedge block.
- b. Provide a cover, shield or similar attachment over the current wedge block to prevent foreign material from entering the wedge block bore.
- c. Provide a mechanism which would wipe the source wire as it travels into or out of the wedge block to remove foreign material that may be present on the source wire.
- d. Modify the bore of the wedge block by lining it with a stainless steel needle through which the source wire would pass.
- e. Modify the bore of the wedge block by increasing the diameter. This would provide a larger gap for foreign material to drop free.

Varian has not seen any problems with the wedge block on units that are in the field and are subject to the periodic maintenance in TechTip -TT-VS-01247. It is not planned to re-fit older units with the new design wedge block

Responsible organization – Varian Brachytherapy is the responsible organization within Varian Medical Systems, Inc.

Length of time that will be taken to complete the action – The maintenance in the Tech Tip will continue for all HDR units in clinical use. The target date for completion of the long term corrective action is April 30, 2012. Alternate long term corrective action may be implemented depending on the outcome of Varian's investigation.

8. Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

Customer Technical Bulletin CTB-VS-640A was issued in February 2009 as a response to Event 44774. All customers have a copy of this bulletin and a copy is attached to this report.

9. In the case of an early site permit, the entities to whom an early site permit was transferred.

Not applicable

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Tech Tip Information

		Approved Release Date: _____	
Title/Subject:	Removing Dirt Build Up	TT Number:	TT-VS-01247
PC/EFF:	Product Code: H60, Product Name: VariSource H600430 to H600505 or as required		
Tools As Required:	No. 70 drill (0.0280" - 0.71mm) No. 69 drill (0.0292" - 0.75mm)		
Reference Documents:	AL25512000 – VariSource Service Manual		

Document Information

REV	CREATION DATE	INT	DESCRIPTION OF CHANGE	File Name
A	Jan. 07, 2009	DS	Initial Release	TT-VS-01247a
B	Jan 14, 2009	DS	Extend Effectivity from 435 – 462 to 430 - 505	TT-VS-01247b
C	August 2009	DS	Changed wording to 'may' from 'can and will' added 'as required' statement to PC/EFF Added some dummy side funnels to be cleaned also	TT-VS-01247c

Part Number Information

Part Number	Description
N/A	

These notes are to provide guidance specifically with cleaning the wedge block on the input to the retract assembly and other areas where dirt can build up. Analysis of the material obtained from field systems has shown it to predominately consist of a mixture of PTFE and nitinol.

If you find a large amount of dirt or have problems during this process please contact PSE (vbt.pse@varian.com) immediately. Do NOT load a new source wire in these circumstances.

1. Areas to Clean

The following are areas within the system where dirt is known to collect.

- Turret
- Home Switch
- Wipe Block
- Funnels on the entry and exit of the V-drive (Active and Dummy)
- **Active Wedge block – note, recent experiences have shown this is a component where excessive build up of may cause the source wire to experience restricted movement. This in turn may result in the need to use the emergency handcrank to return the source to the parked and shielded position.**

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AUTHOR	DATE	CHECKED BY ENGINEERING	DATE	PSE MANAGER	DATE
Dave Stewart		Chris Heath		Richard Dillon	
					SHEET 1 OF 3
					TT-VS-01247
					c REVISION

2. Cleaning

2.1. Turret

Ensure the turret area particularly the brass ring and the flag of the Quick Connects are clear. Use an alcohol wipe

2.2. Home Switch

Dismantle the switch and clean out any of the dirt which has built up on any of the surfaces

2.3. Wipe Block

Simply open and clean

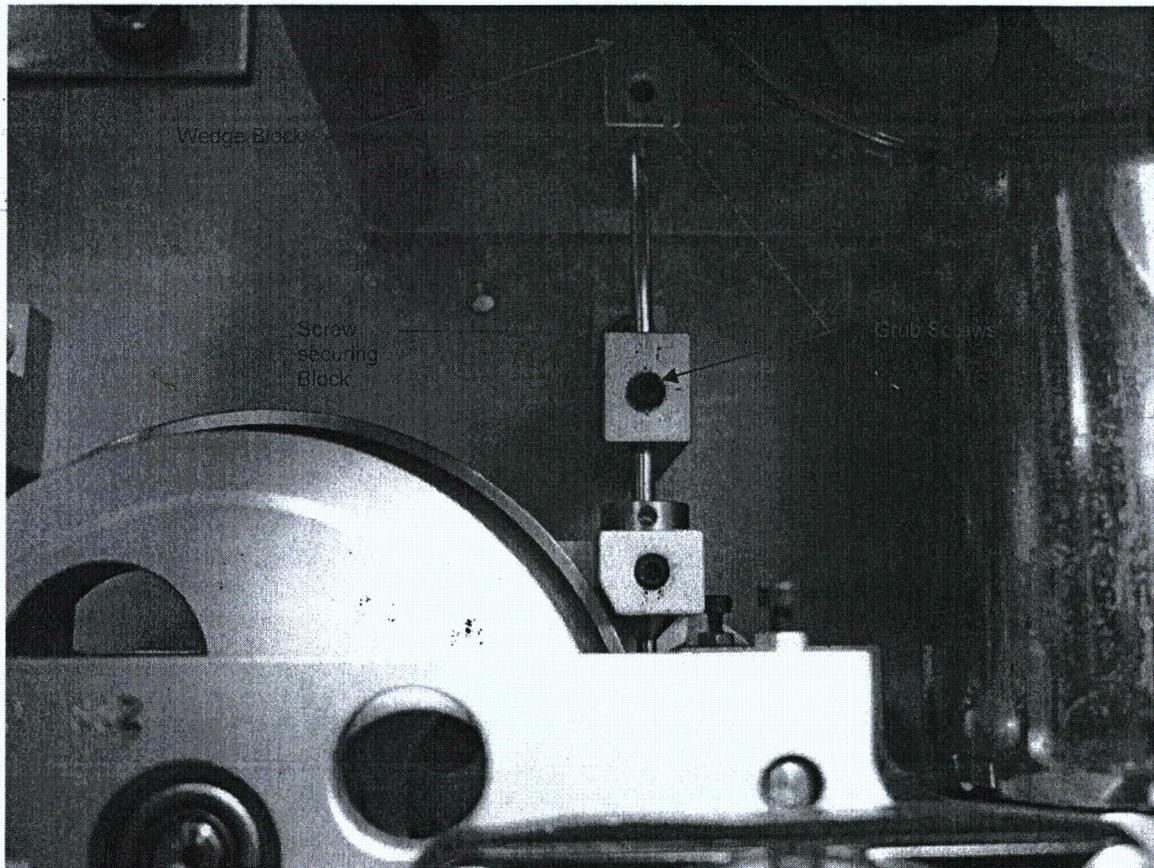
2.4. V-Drive Funnels (Active and Dummy)

Remove the V-drive and clean out the funnels on the entry and exit.

2.5. Active Wedge Block

1. Remove the V-drive

2. Loosen the two grub screws securing the tube which leads into the wedge block (using a 1.5mm A/F hex key) and slide the tube downwards to remove.



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Revision

TT-VS-012471247

SHEET
2 of 3

3. Note the required drill sizes at the end of this procedure, and where to get them (US only). DO NOT use any other drill sizes as this will cause damage to the components.
4. Remove the block in between the V-drive and wedge block to gain access to the underside of the hole. The one displayed in this picture shows the screw on the active side of the track plate. Some machines may have the screw through an identical block on the dummy side of the plate.
5. **Using a No. 70 drill (0.0280" - 0.71mm) first.** Insert it into a pin chuck so that 27mm is visible from the end. This is so that the wheel and pinch rollers are not damaged by the drill going too far through the wedge block.
6. Gently use the drill to clean out any black material from beneath.
7. Swap to the larger No. 69 drill (0.0292" - 0.75mm) and repeat.

This hole varies in size between 0.711mm and 0.813mm so this second drill may not fit.



CAUTION: This process should NOT remove any metal, it is meant solely to remove any build up of debris.

2.6. Reassembly

When reassembling the tube into the wedge block, note that the distance extending underneath the mounting block (ie, the distance extending into the V-Drive funnel when fitted, shown on the diagram) should be 10.5mm.

All other components should be fitted in accordance with the service manual instructions.

3. Drill Details

As these drills may be difficult to source in the US we have found the following supplier:
http://www.wttool.com/product-exec/product_id/22555/nm/Number_Size_Jobber_Drills_WT_Import

- Part No 0142-0346- No 70 drill (0.0280" - 0.71mm)
- Part No 0142-0341- No 69 drill (0.0292" - 0.75mm)

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Title	Potential for a source wire path constriction inside the VariSource™ HDR afterloader.	
Date		Initial Release: 02/03/2009

Est. labor hours	N/A	CTB	CTB-VS-640A
		DWG. No.	N/A

Purpose	To inform VariSource users of the potential for a source wire path constriction inside the afterloader.
Effectivity	VariSource ID, 200 and iX Afterloaders.
Prerequisites	

REV	DATE	STB	INT	DESCRIPTION OF CHANGE	FILE NAME
A	02/03/09	N/A	JM	Initial Release	CTB-VS-640A

Tools & Equip	N/A
Reference Documents	

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Created By John Morrison	DATE	MARKETING	DATE	REGULATORY	DATE	Engineering	DATE	Operations	DATE	Tech Support	DATE	SHEET 1 OF 5	
Checked By Wayne Snyder	DATE	Tim Clark		Mark Kattmann / Paul Verdon / Juergen Handke		Ted Jackson		Mark Kattmann / Ken Mills / Wolfgang Zindler		Robert Cardell		CTB # CTB-VS-640A	REV A

POTENTIAL FOR A SOURCE WIRE PATH CONSTRICTION INSIDE THE VARI-SOURCE™ HDR AFTERLOADER.

1. OCCURANCES

Three recent events have occurred in which the source wire has become stuck inside the VariSource HDR afterloader. The incidents have all occurred with Varian Service personnel present, and during active source wire retraction in the course of Positional Verification Testing (PVT), performed as part of the normal source wire exchange process. The constrictions have occurred internally, and in each case were caused by material buildup in the wire path. The source wires were all retracted into the VariSource safe by Varian service personnel using the manual emergency retract mechanism. Patient treatments have not been affected.

2. AFFECTED DEVICES

The path constriction has occurred in HDR units within a short range of serial numbers, H600435 through H600460. While we think that the likelihood of an internal path constriction is low outside the stated range of serial numbers; this notice is being distributed to all VariSource afterloader sites as a precautionary measure.

3. RECOMMENDATION

Please take this time to review your emergency procedures in the event the source wire must be retracted using the manual retract handle.

In addition, please immediately report any errors that occur upon active wire retraction with error code 1A, class 2, "Active wire drive slippage ..." This user resettable error occurring during active wire retraction may be an indication that the VariSource is trending toward an internal path constriction. If during active wire extension you encounter the same error, it is recommended that you clear the error normally and inspect the transfer guide tube and applicator connection. If you can determine the cause of the drive slippage error (for instance a path obstruction), there is no need to contact Varian Service personnel.

If you have any questions about this bulletin please contact Varian BrachyTherapy using the contact information on page 4.

Page 2 OF 5	CTB-VS-640A	N/A DWG NO.	A REV	ATTENTION: This information is provided for use by Varian Medical Systems Customers and Service Representatives. Customers are assumed to have received the training recommended for the use of the indicated product Copyright © 2009, Varian Medical Systems, Inc. All rights reserved.
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Varian BrachyTherapy
700 Harris Street
Suite 109
Charlottesville, VA 22903

RECIPT VERIFICATION CARD

Customer receipt verification:

Fill out the Receipt Verification Card and FAX or e-mail immediately To Varian
BrachyTherapy:
866-385-1322, or (949) 221-7631

CTB Number: A

Product Code:

Serial Number:

Name of Institution:

Date of Receipt:

Customer Name:

Comments:

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Varian BrachyTherapy Technical Support Contacts

Toll Free Telephone Support

Country	Access number	Country	Access number	Country	Access number
Australia	1 800 144 130	Hungary	06 80013 318	Norway	800 16 327
Belgium	0800 74 248	Indonesia	001 803 0441 1109	Portugal	800 880 183
Canada	1 888 226 8633	Ireland	1 800 551 716	Singapore	800 44 11 100
Denmark	80 88 07 45	Israel	1 800 944 11 80	Spain	900 957 680
Finland	0800 11 68 92	Italy	800 790 535	South Africa	0800 992 872
France	0800 905 397	Japan	00531 78 22 21	Sweden	0200 21 45 08
Germany	0800 182 6937	Luxembourg	0800 25 67	Switzerland	0800 83 75 77
Holland	0800 022 5072	Malaysia	1 800 808 605	Taiwan	0080 04 40 99
Hong Kong	0800 96 21 42	New Zealand	0800 445 938	UK	0800 068 06 88
USA	1 800 360 7909				

In addition, toll free access using the AT&T International direct dialing network is available in over 150 countries. To access this number, dial first the AT&T access number in your area (for the access code in your area, see internet address: http://www.business.att.com/bt/dial_guide.jsp)

Then after hearing the AT&T signature noise, and, "Please enter the number you are calling", dial: **800-360-7909**

For countries not listed above or not in the AT&T International dialing network, Telephone Support may be obtained via the following numbers:

UK: +44 1293-601-327

USA: +1-434-979-1540

Our Applications Specialists can immediately return any calls received on these numbers.

Fax Support

Please fax your questions to BrachyTherapy Technical Support on:

UK: +44 1293-542-626

USA: +1-866-385-1322

+1-949-221-7631

e-Mail

To submit a support request or general inquiry, please compose an email with a blank subject line, to: brachyhelp@varian.com. Please indicate the name of your institution, your name and phone number, the product you are commenting on, and your system number (if known), as well as the description of the problem or question.

www

Note that Customer Technical Bulletins for Varian Medical Systems may be found on the internet at: <http://my.varian.com/> You must register and log in to view support information. CTB's are organized by year of issue and title.

Page 4 OF 5	CTB-VS-640A	N/A DWG NO.	A REV	ATTENTION: This information is provided for use by Varian Medical Systems Customers and Service Representatives. Customers are assumed to have received the training recommended for the use of the indicated product Copyright © 2009, Varian Medical Systems, Inc. All rights reserved.
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CH-6303 Zug
Tel: 41.41.749.8844

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Crawley
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Tel: 44.1293.53.12.44

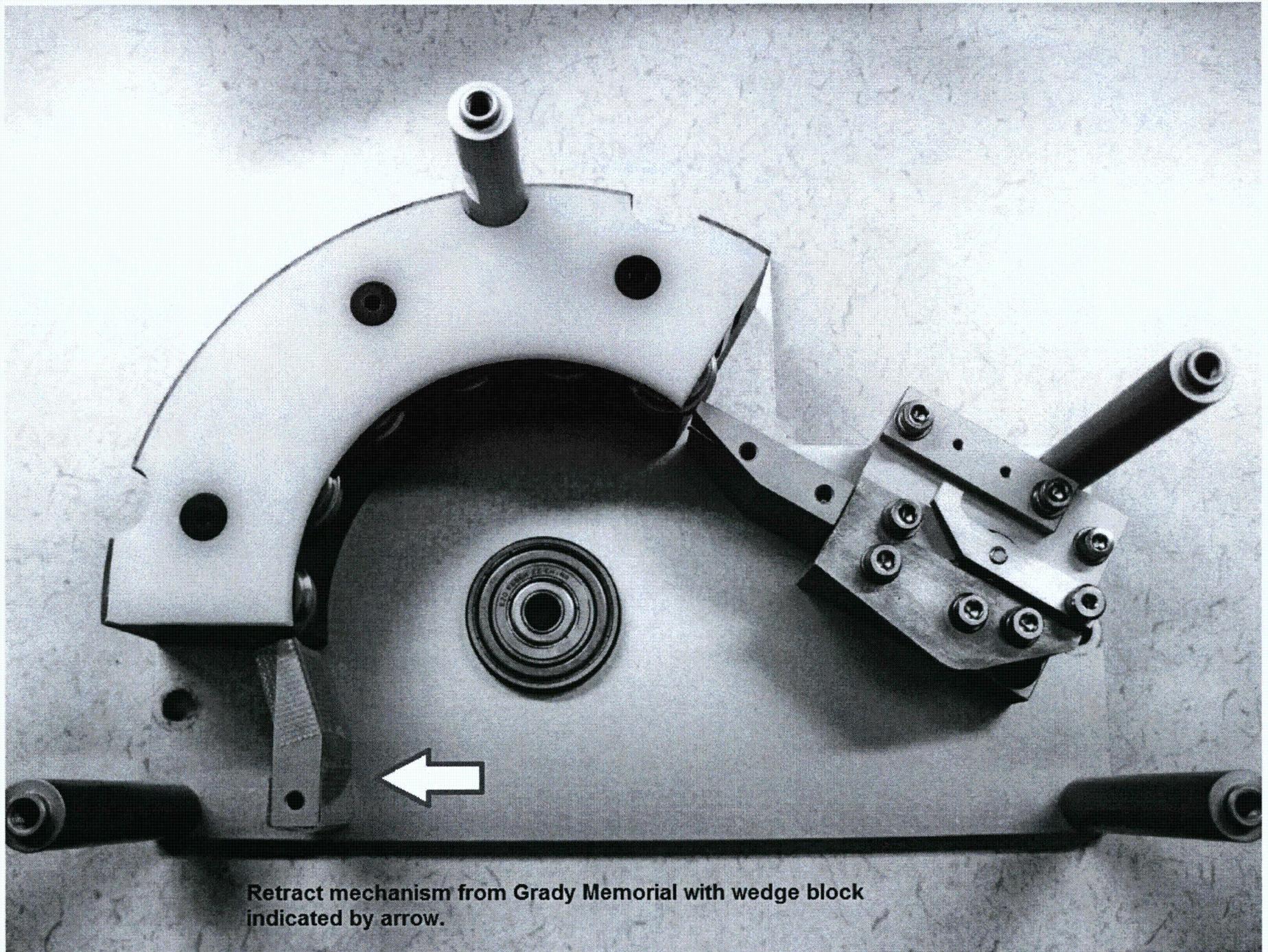
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X-rays and photographs of wedge block

Grady Memorial – Atlanta GA

Description of images – Event 46758

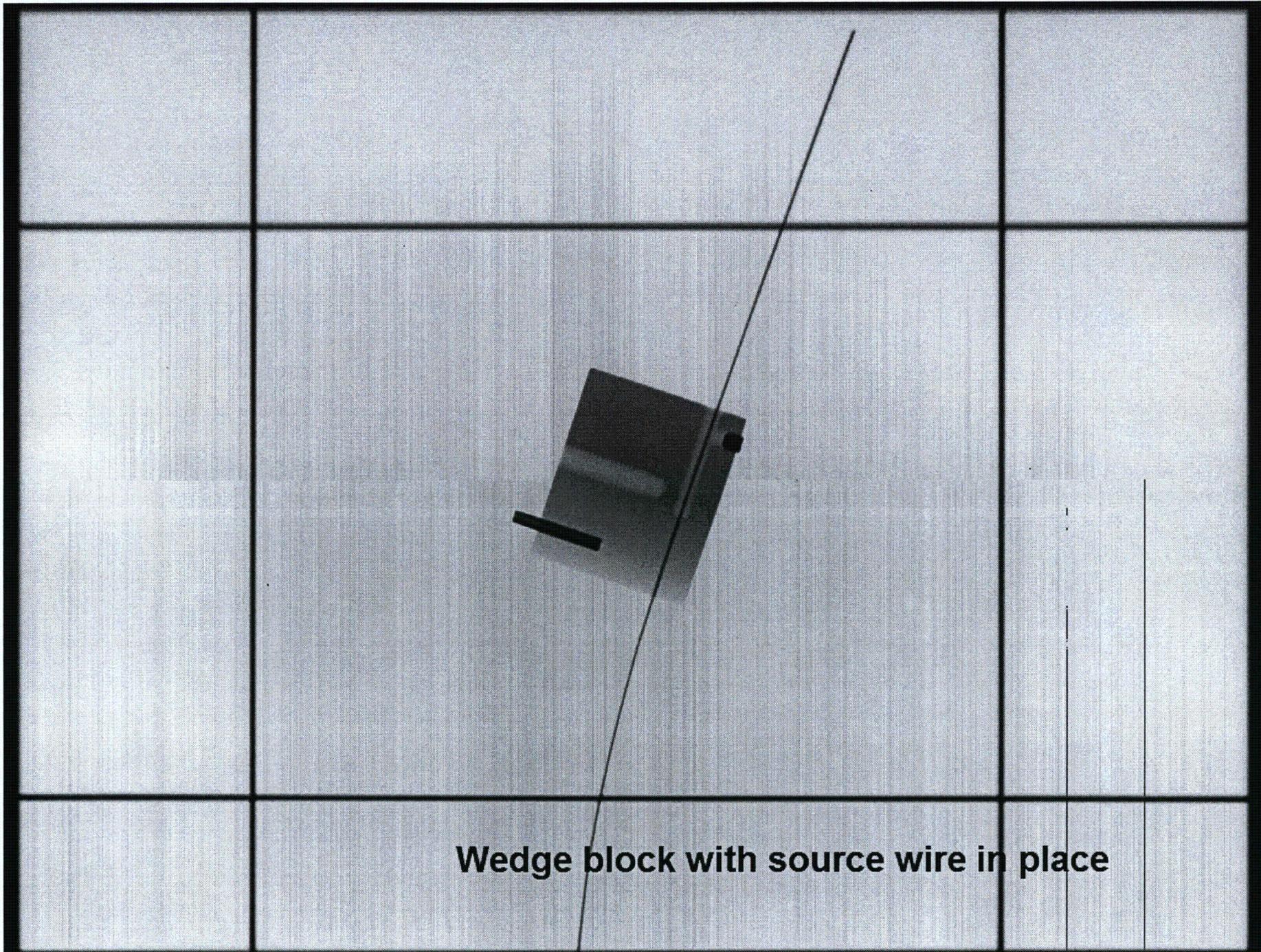
1. **Retract mechanism from Grady Memorial – wedge block on lower left.** This is the component involved in the event at Grady. The wedge block in its proper orientation is identified by the arrow.
2. **Wedge block from a Varian test unit...** This is from a test unit at Varian Charlottesville that has 1,612,300 cycles on the wedge block. The debris is the material of interest in Event 44774.
3. **Wedge block with source wire in place.** This shows the source wire as it fits through the bore of the wedge block.
4. **Wedge block.** X-ray at oblique view of the wedge block. When installed on the HDR unit the right side of the wedge block is at the top and the wire travels through the length of the wedge block. The source wire is only out of the wedge block when a source exchange takes place. Otherwise, the lumen of the bore is always occupied as the wire moves forward and back with each extension and retraction
5. **Wedge block 2 .** X-ray view, showing the exit of the bore to the right. The bore exits on the angled face of the wedge, therefore, it does not extend to the far edge of the image.
6. **X-ray – bore size transition in wedge block.** Close up view of the transition of the bore size. Slight deposition of material is seen, though it cannot be quantified. The bore diameter is nominally 0.7mm.
7. **Bore exit at the top of the wedge block.** Close up view of the exit of the bore on the angled face of the wedge block. In real life it looks like the end of a hypodermic needle, as if one were to cut through a hollow needle at an angle.
8. **Monocoil swab 1.** View of the monocoil sheath that is used to cover, protect and secure the tail end of the source wire while it is installed in the shipping container. Some debris is seen on the swab. Source wires are cleaned as part of the installation procedure.
9. **Monocoil swab 2.** Close up view of the swab taken of the interior of the monocoil sheath.
10. **X-ray of monocoil sheath used to secure source in shipping container.** X-ray through several coils of the monocoil sheath while investigating if there was anything on the internals of the sheath that might contribute to the event.
11. **Monocoil sheath view 2.** X-ray of the tail of the sheath showing the stopper/closed end.
12. **Connector – monocoil sheath to shipping container.** X-ray of the connector that joins the monocoil sheath to the shipping container.
13. **Wedge block bore endoscope 1.** Close up endoscopic photo into the bore of the wedge block involved in the event.
14. **Wedge block bore endoscope 2.** Wider angle endoscopic view into the bore of the wedge block with an area of interest highlighted. There was no clear decision if the area of interest was anything more than random manufacturing markings.
15. **Wedge block bore endoscope 3.** Close up view of the area of interest. Nothing definitive was identified.



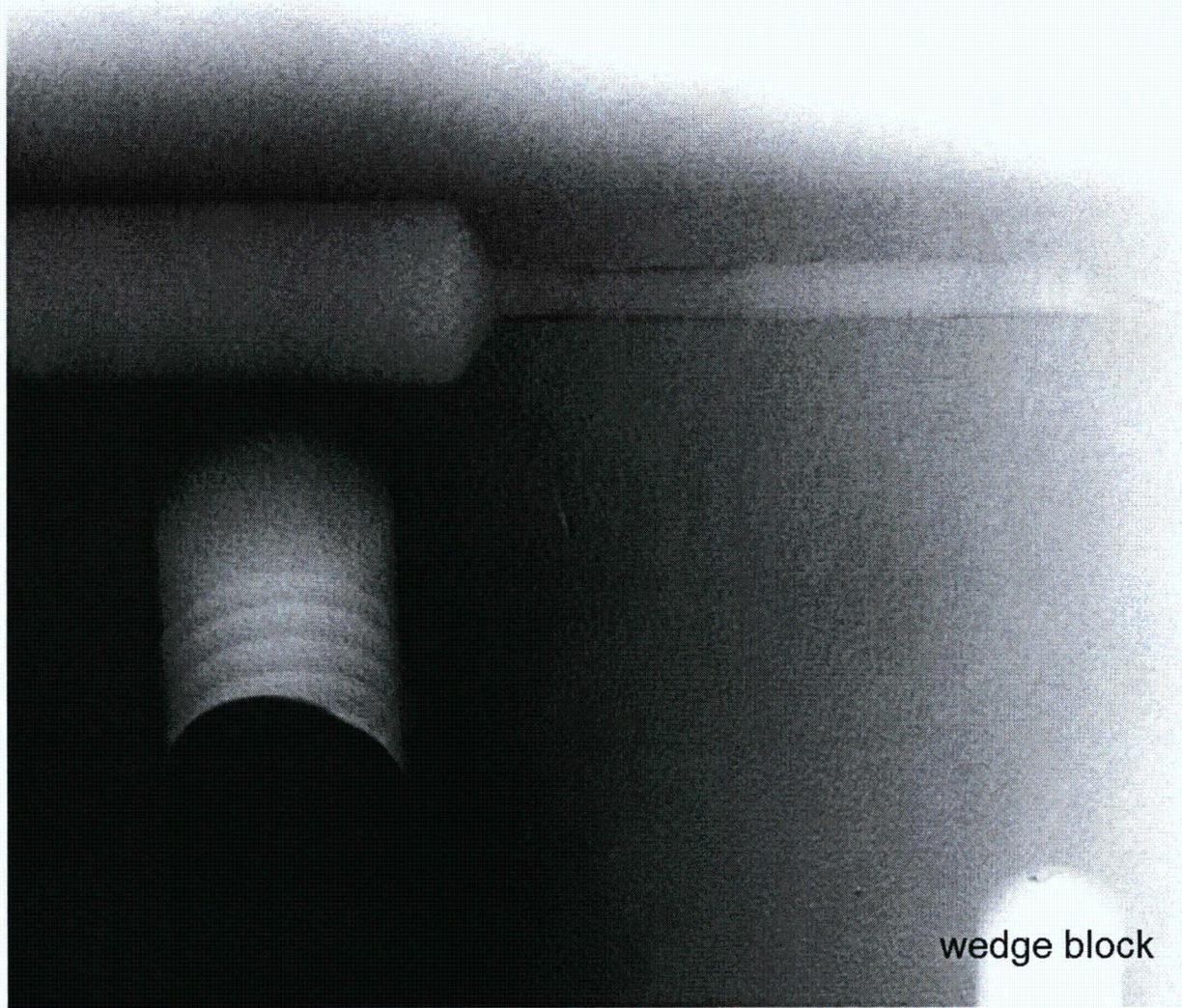
Retract mechanism from Grady Memorial with wedge block indicated by arrow.



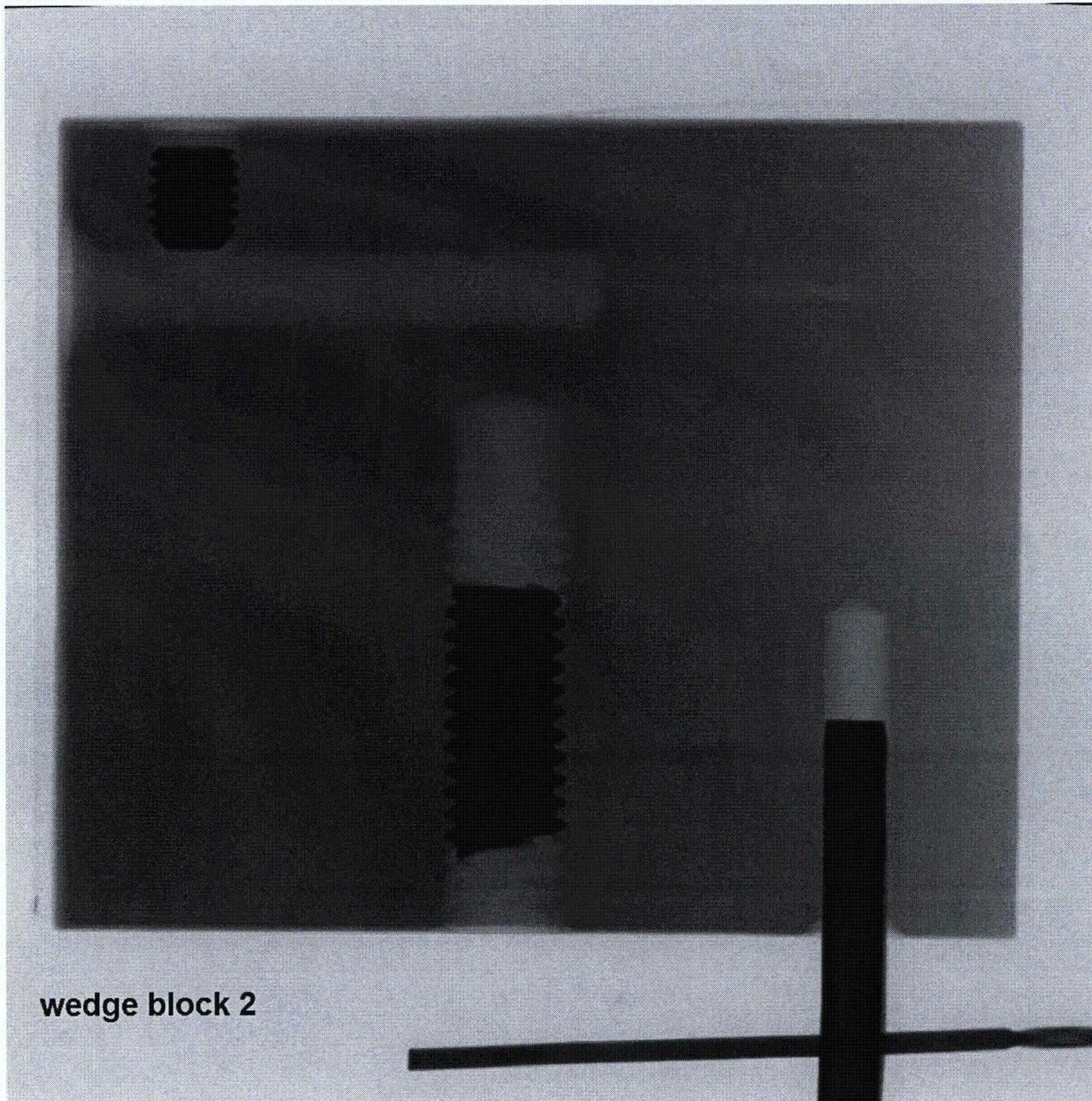
Wedge block from a Varian test unit. This particular wedge block has 1,612,300 cycles through it without failure. This is the 'as removed' condition. The debris was removed from the bore.



Wedge block with source wire in place



wedge block



wedge block 2

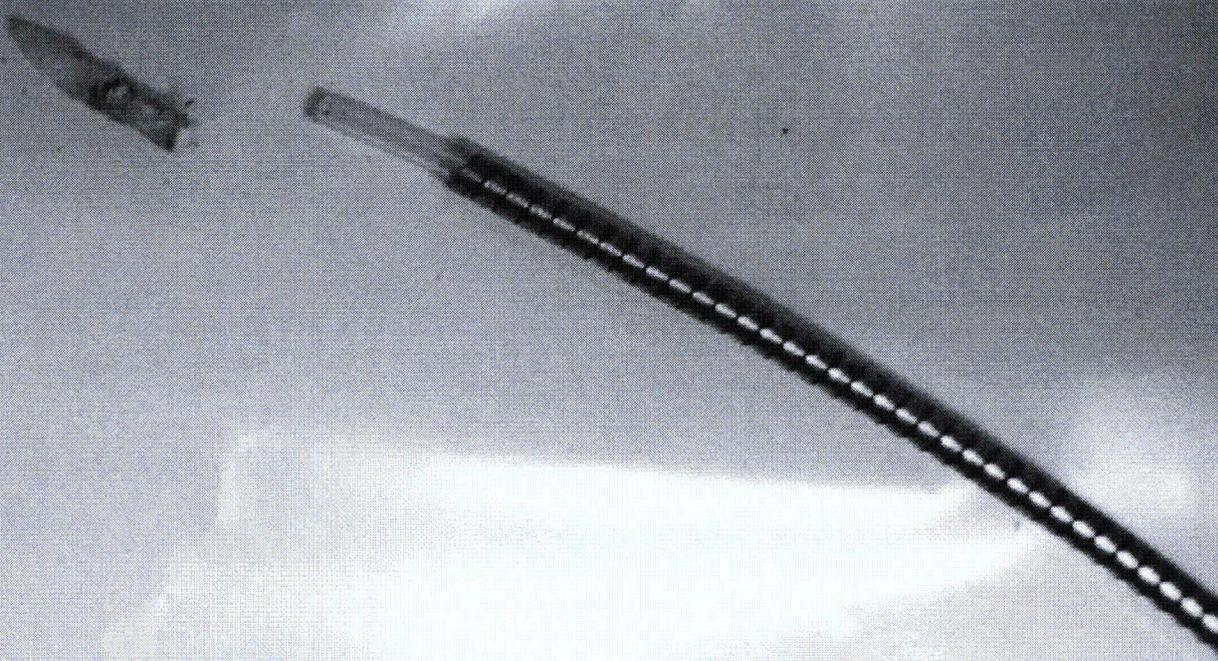


x-ray - bore size transition in wedge block



bore exit at the top of the wedge block

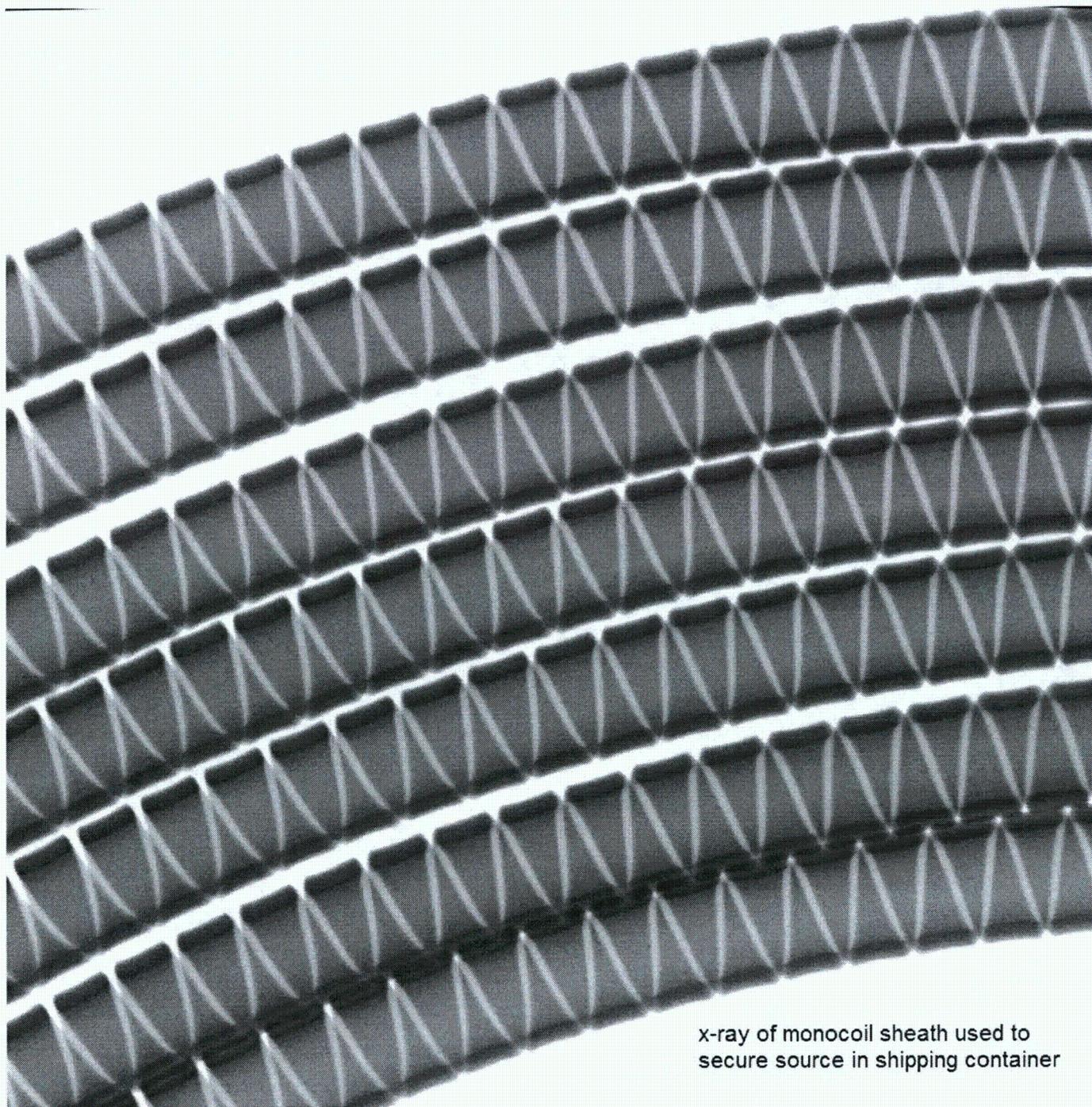
SECTION #3



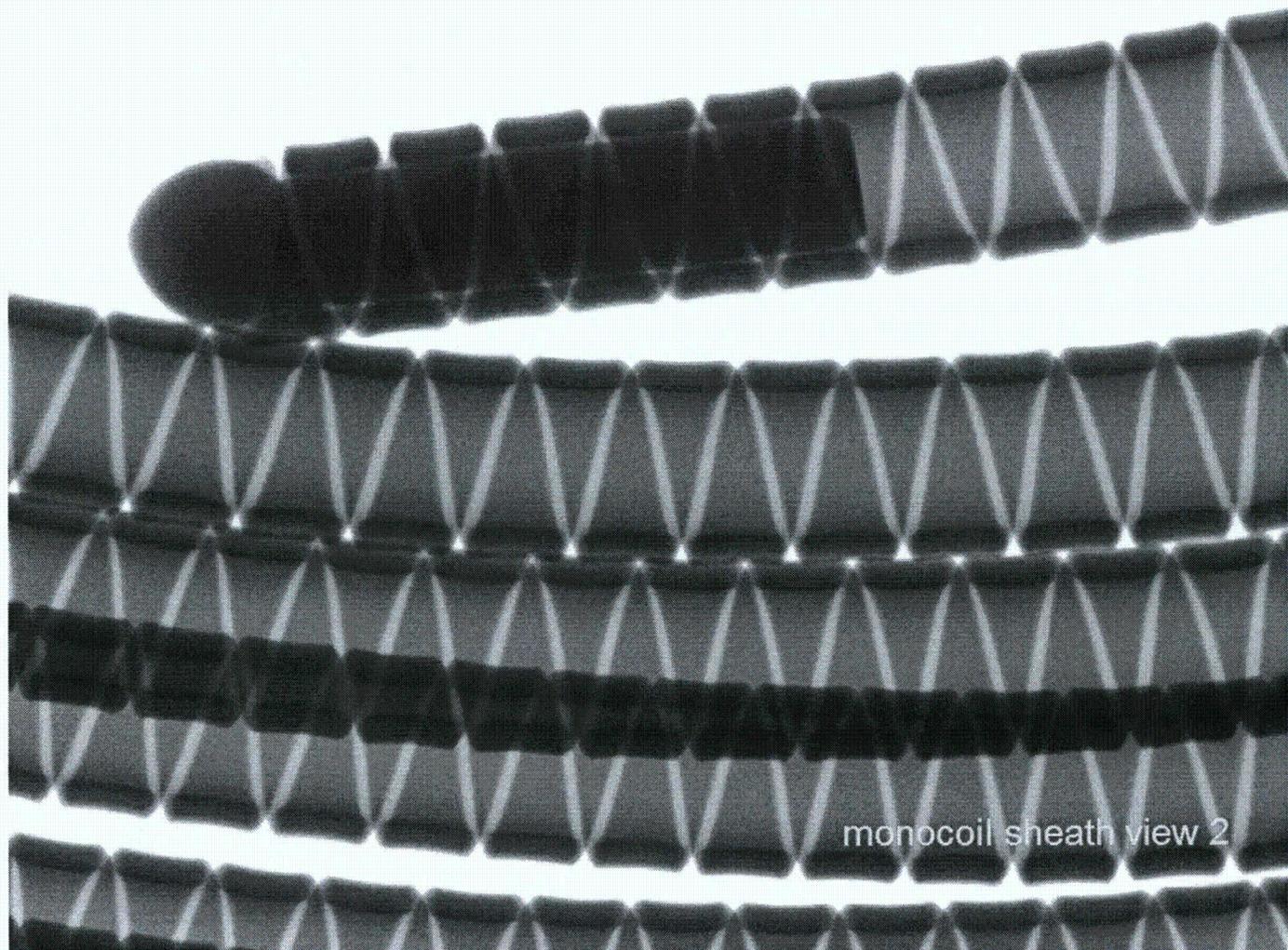
monocoil swab 1

SECTION #2

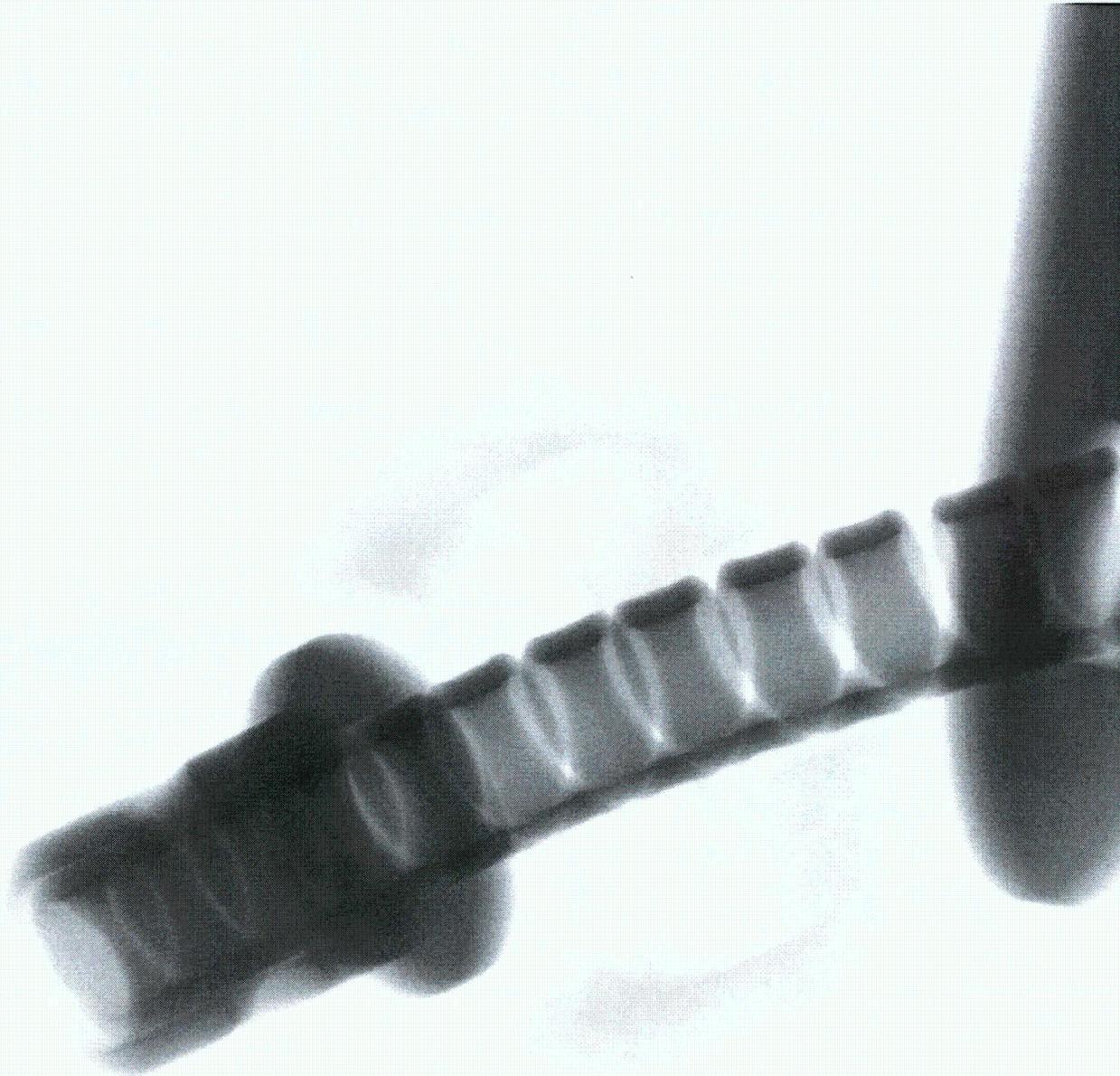
monocoil swab 2



x-ray of monocoil sheath used to
secure source in shipping container

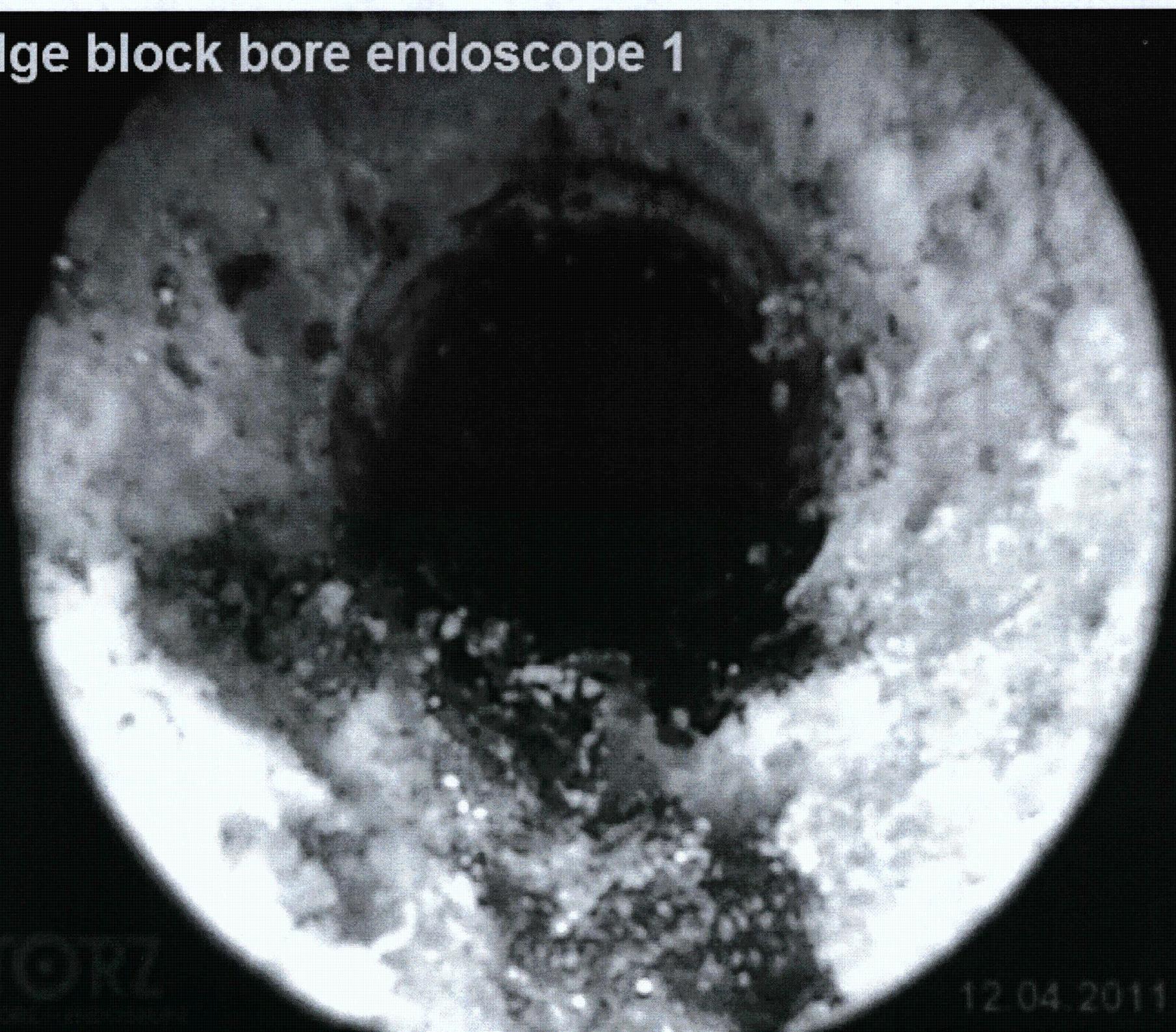


monocoil sheath view 2



connector - monocoil sheath to shipping container

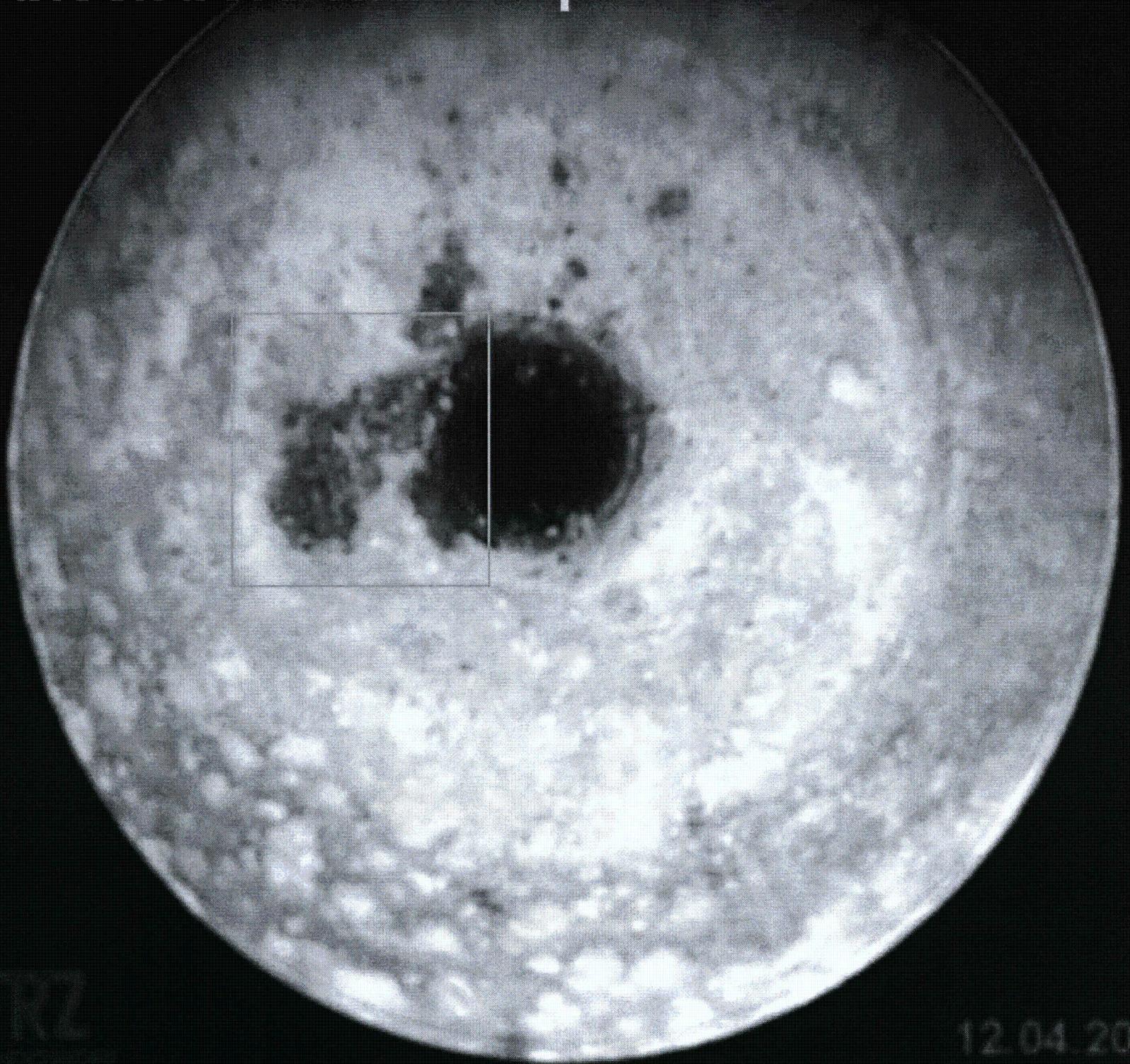
wedge block bore endoscope 1



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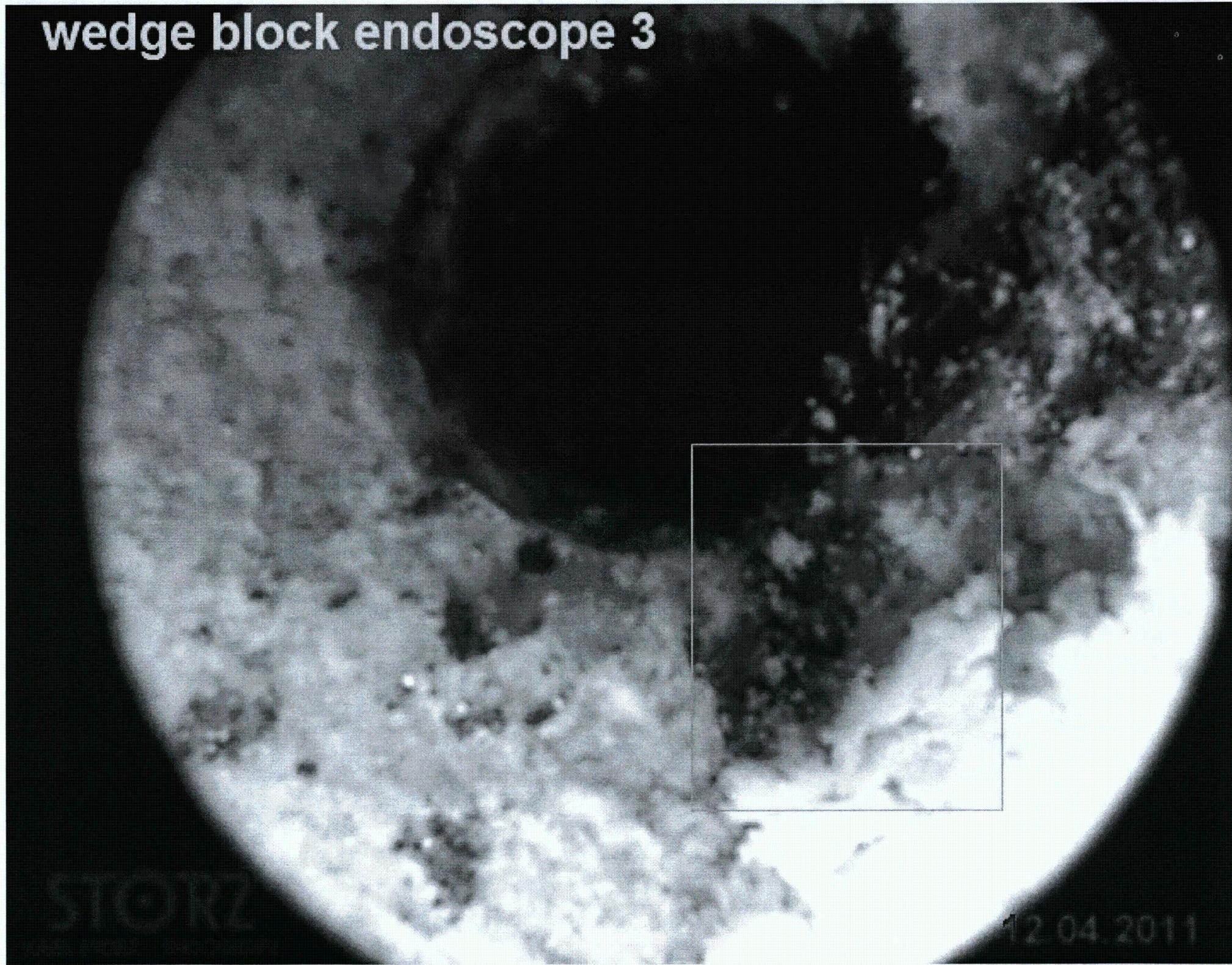
wedge block bore endoscope 2



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wedge block endoscope 3



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