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SmithNephew

«УТВЕРЖДАЮ»
Руководитель отдела
регистрации и нормативно-правовой
документации

ООО «Смит энд Нефью»
Хайруллина А.А.



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«21» августа 2022 г.

ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ МЕДИЦИНСКОГО ИЗДЕЛИЯ:

«Винт интерферентный BIOSURE REGENESORB»

производства

Смит энд Нефью, Инк. Эндоскопи Дивижн / Smith & Nephew, Inc. Endoscopy Division

2022

 smith&nephew

BIOSURE® REGENESORB
INTERFERENCE SCREW

5MM x
25MM

MP 72204390

QTY: (1)

LOT 51047072

EXP 2025-07-11

EN Interference Screw DE Interferenzschraube NL Interferentieschroef IT Vite
a interferenza FR Vis d'interférence ES Tornillo interferencial TR Enterferans
Vidası PL Śruba interferencyjna PT Parafuso de interferência NO
Interferensskruer SV Interferensskruv DA Interferensskruer FI Interferenssiruuri
CS Interferenční šroub RO Șurub de interferență EL Βίδα παρεμβολής HU
Interferenciassavar

MADE IN USA

EXP 2022-07-11

Endoscopy Smith & Nephew, Inc.
150 Minuteman Road
Andover, MA 01810 USA

Smith & Nephew Operations B.V.,
Blaaslaan 2, 2132 NP
Hoofddorp, Netherlands

EXP 2025-07-11

(01) 00885554038884 (12) 260711 (10) 51047072

(11) 220711

STERILE EO CE MR

MD Rx only

This product may be covered by one or more U.S. patents. See
smith-nephew.com/patents for details.

* Trademark(s) of Smith & Nephew.

77°F/25°C

Internal Use Only
J02V61C1AA, 1

Endoscopy
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F +1 978 749 1108

Customer Service
+1 800 343 5717

www.smith-nephew.com

R_x
ONLY

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5MM x
25MM

RFP 72204390

QTY: (1)

LOT 51047072

EXP 2025-07-11

STERILE EO

Стерильная упаковка на примере варианта исполнения: Винт интерферентный BIOSURE REGENESORB 5 x 25 мм

smith & nephew

72204390

51047072

QTY: (1)

UDI



(7) 25071

(0) 51047072

GTIN: 00885554036664

BIOSURE® REGENESORB
INTERFERENCE SCREW
5MM x 25MM

MD



MR



2022-07-11

2025-07-11

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Andover, MA 01810 USA

Smith & Nephew Operations B.V.,
Bloemlaan 2, 2132 NP
Hoofddorp, Netherlands

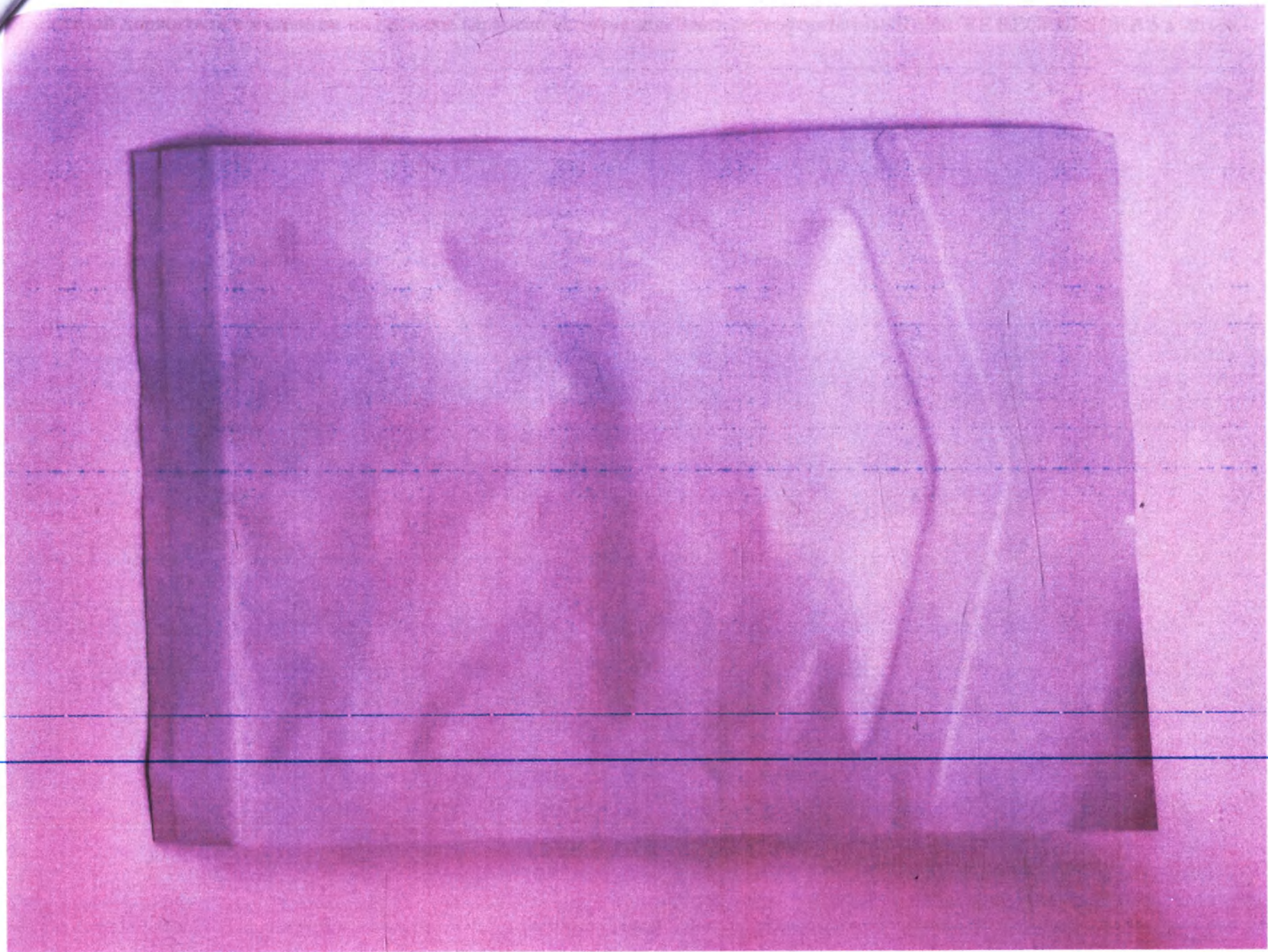
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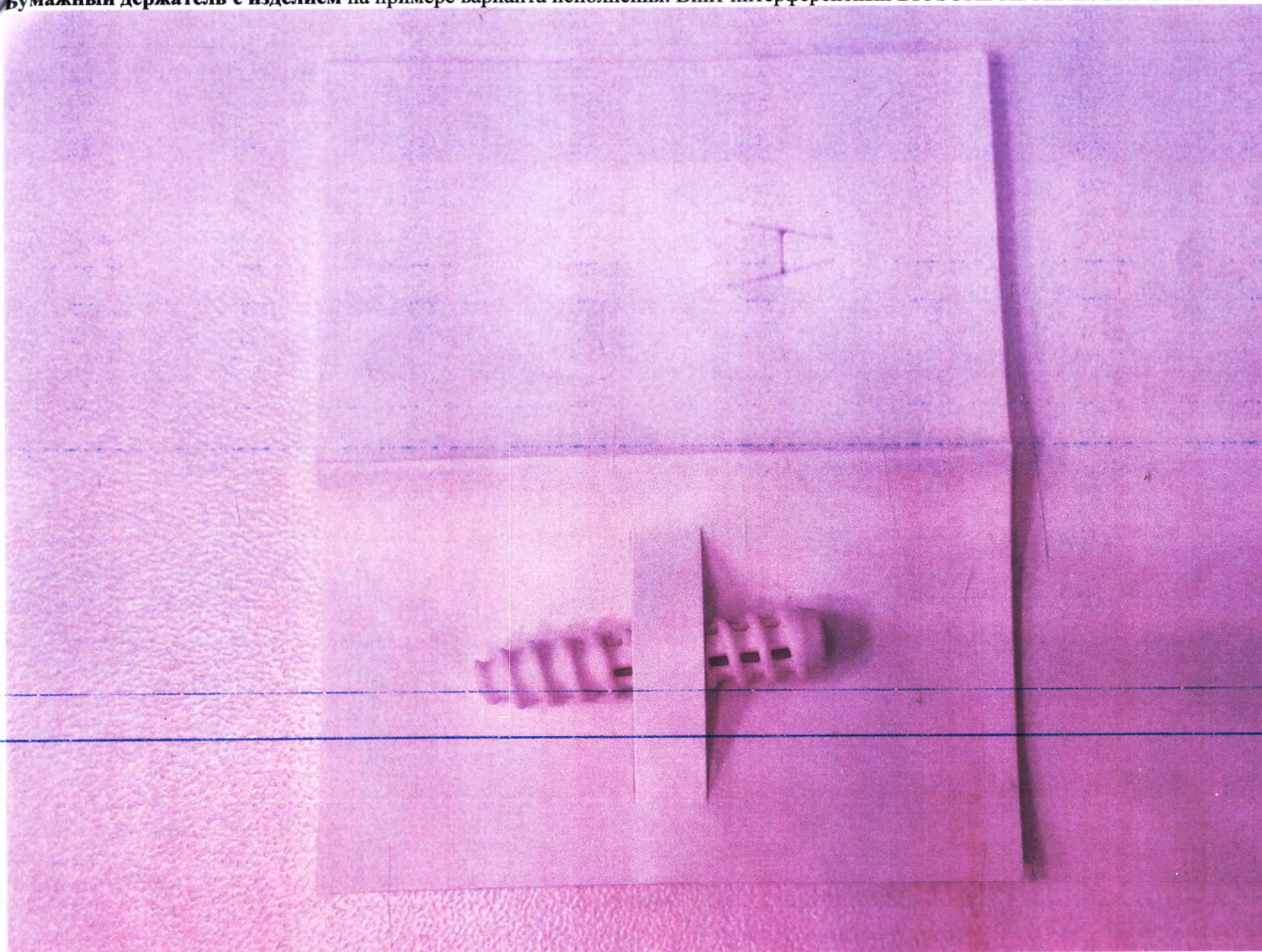
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STERILE EO C E Rx only 2797



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BIOSURE® REGENESORB
INTERFERENCE SCREW
5MM x 25MM



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Hoofddorp, Netherlands



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(11) 220711

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INTERFERENCE SCREW
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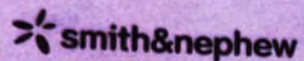


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INTERFERENCE SCREW
5MM x 25MM

2025-07-11

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BIOSURE® REGENESORB Interference Screw

INSTRUCTIONS FOR USE

Device Description

The Smith & Nephew BIOSURE® REGENESORB Interference Screw is an absorbable biocomposite interference screw with open lateral surface area for use in the fixation of ligament, tendon, soft tissue, or bone-tendon-bone repairs in knee procedures.

The interference screw is provided sterile, for single use only.

How Supplied

The interference screw is provided sterile, for single use only.

Material

The interference screw is made from PLGA (poly(lactic-co-glycolic acid)), β -TCP (beta tricalcium phosphate), and calcium sulfate.

Contents

The interference screw contains:

- 1 ea Absorbable biocomposite interference screw

Refer to individual product labels for the diameter and length of the screw.

Intended Users

The BIOSURE REGENESORB Interference Screw is intended for use by health care professionals in accordance with these

Target Patient Groups

The patient population is comprised of patients for whom the reattachment of ligaments, tendons, soft tissue, or bone tendon bone grafts during orthopedic procedures is determined to be necessary by the operating surgeon.

Expected Clinical Benefits

The expected clinical benefit for the BIOSURE REGENESORB Interference Screw is improvement over pre-operative functional activity of the knee.

Links to the Summary of Safety and Clinical Performance (SSCP)

For use in the European Union (EU), a summary of safety and clinical performance (SSCP) has been developed in conformance with the EU regulations. Specific information about the subject devices, including references/catalog numbers, manufacture name, and tradename, may be used to search for the appropriate SSCP on the European database on medical devices (EUDAMED). Multiple elements of information may be needed to adequately identify the device in EUDAMED. This is the SSCP

ПРОШТО И
ПРОНУМЕРАВАНО
10 ЛИСТОВ

