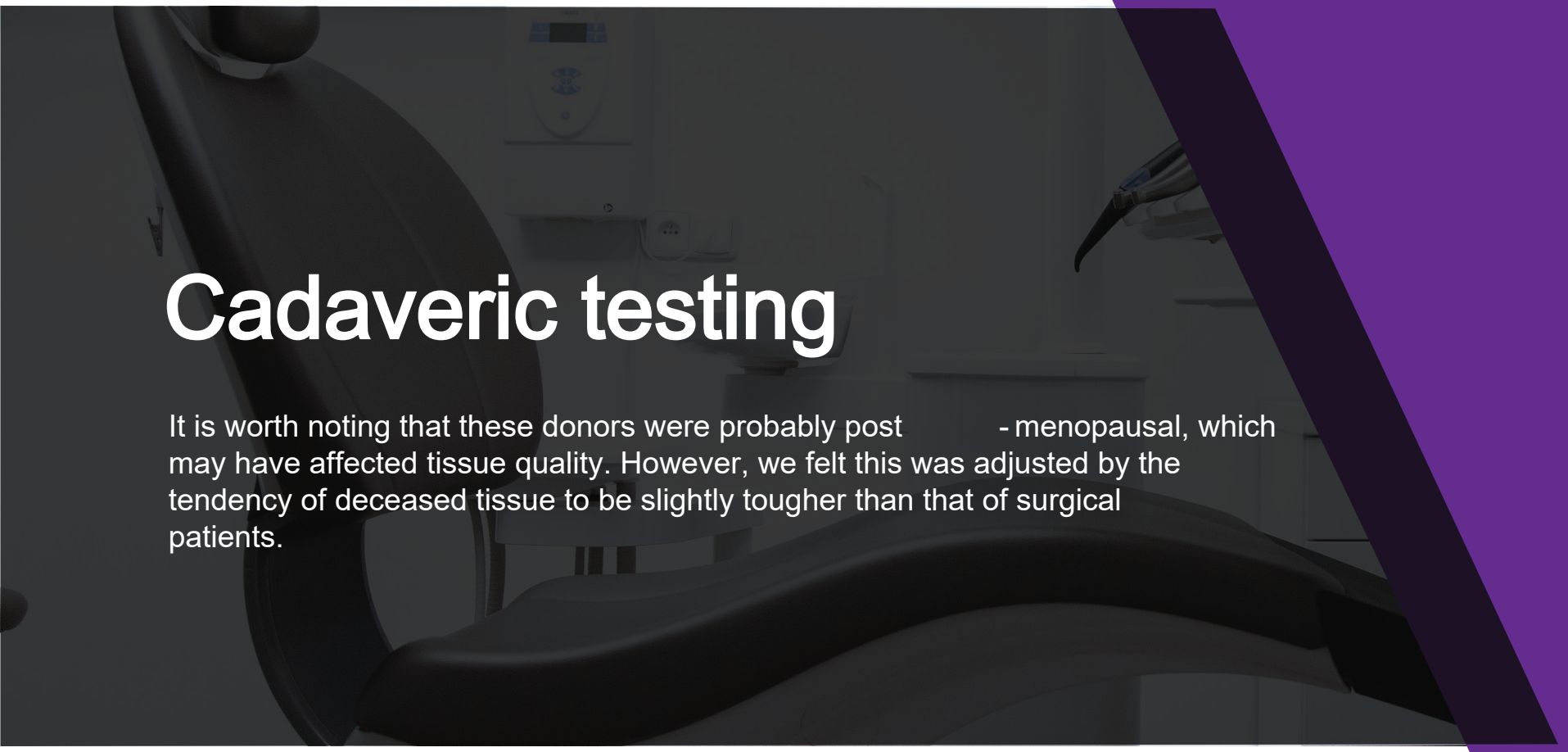
GALAXY II

Cadaveric testing

We investigated stay integrity and maximum sustainable pull force when attached to human tissue. For this we utilized 4 fresh, frozen, non - embalmed human cadaveric whole - body specimens from the Glasgow University donor programme.



Cadaveric testing

It is worth noting that these donors were probably post - menopausal, which may have affected tissue quality. However, we felt this was adjusted by the tendency of deceased tissue to be slightly tougher than that of surgical patients.

Selection for this investigation

21 blunt
5mm hooks

21 Galaxy II
Surgical sharp
5mm hooks

The stay hook was attached to the cadaver in 3 locations and the elastic end attached to the gauge meter

Vaginal wall

Labia

Rectus Fascia

Each stay was pulled to a maximum of 16N. Once tissue started to separate, tension was released to prevent tissue ripping.

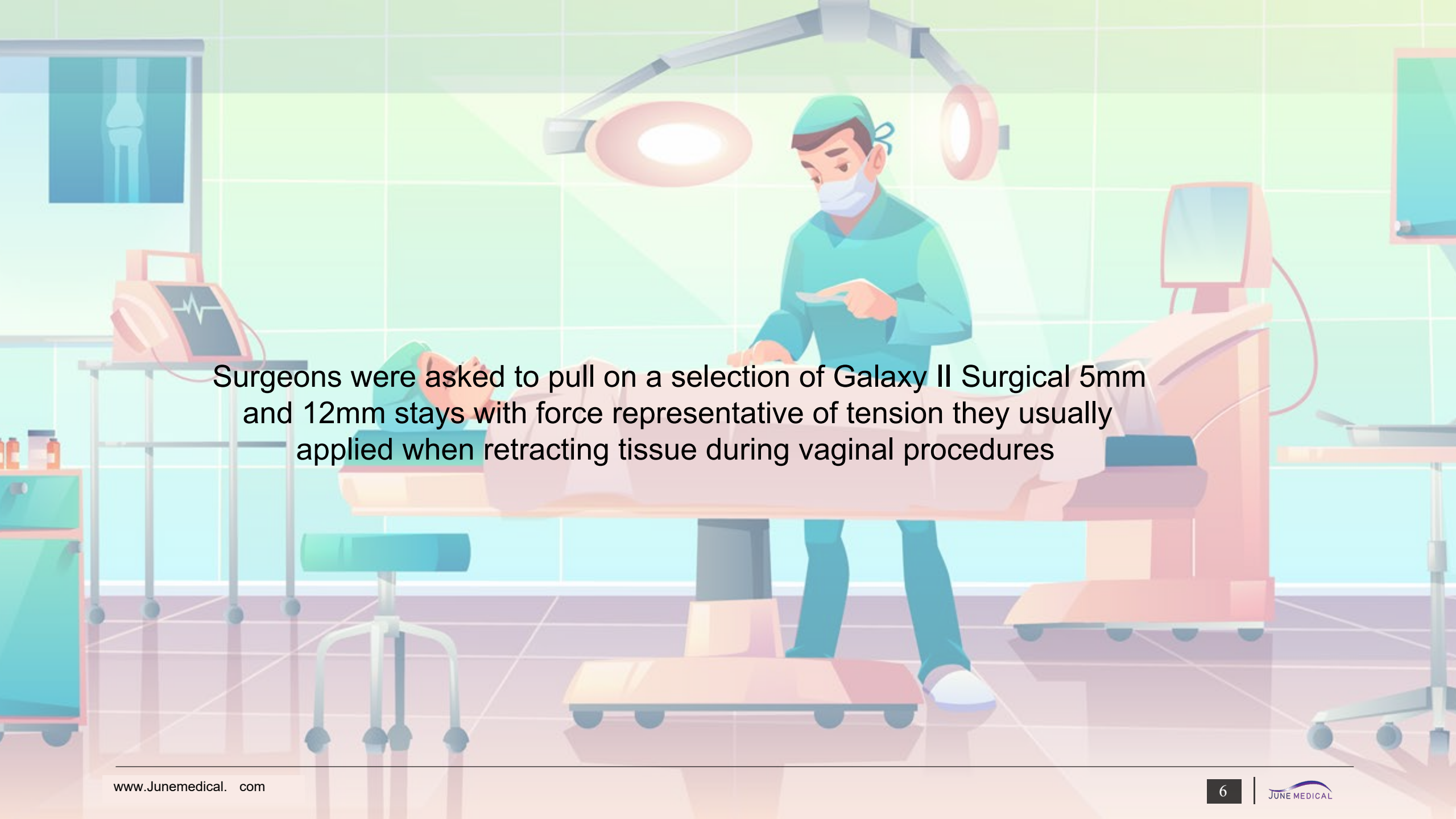
All testing was done with the utmost respect for the donors, and no visible injuries were made.

Tissue separation

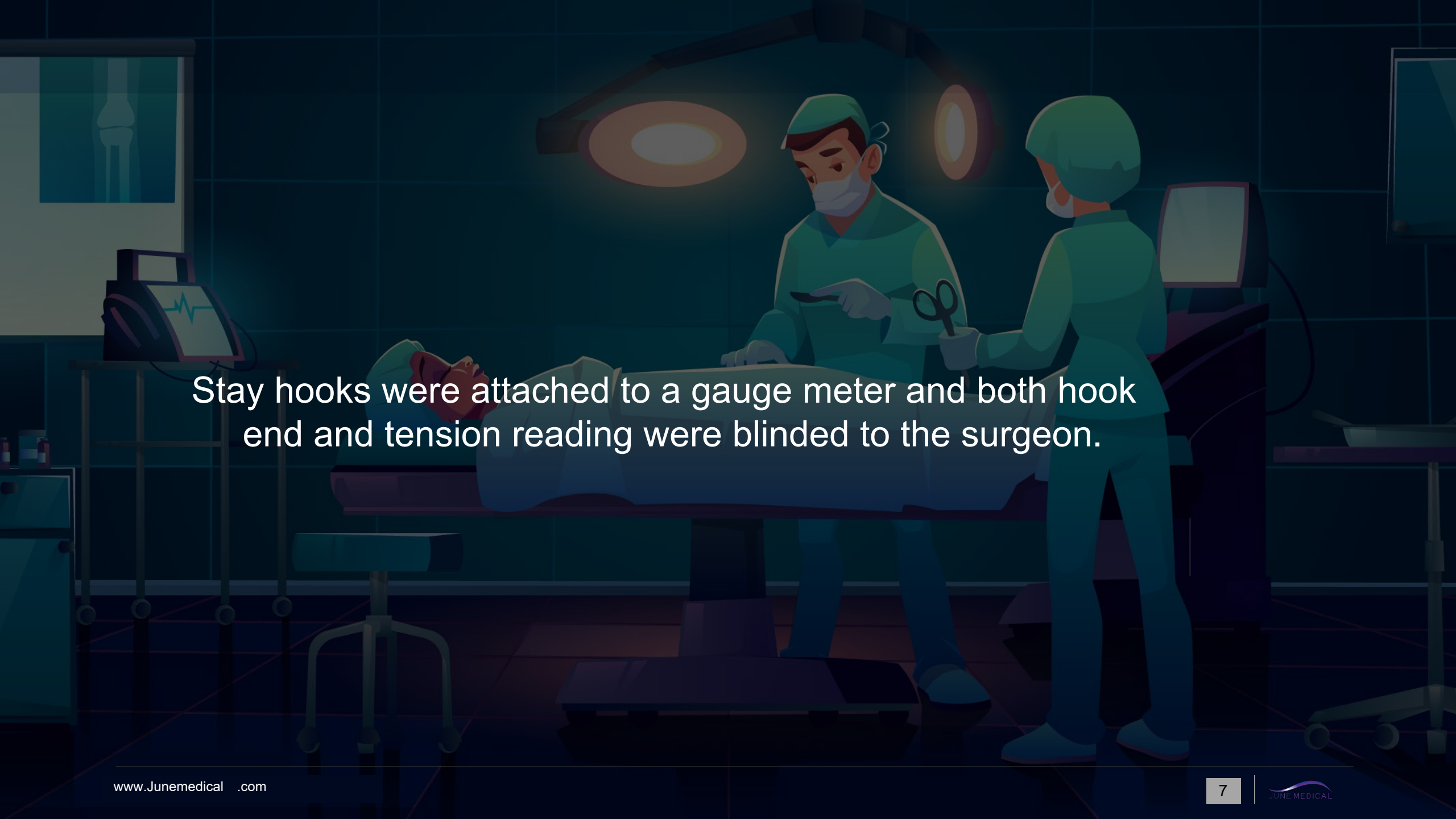
Using sharp 5mm stay hooks in the vaginal wall, we found that this tissue started to come apart at 3–7N

The blunt 5mm stay hooks were placed in the rectus fascia . This tissue started to come apart at 5–10N

Both sharp and blunt 5mm stay hooks were tested in the outer labia, which started to come apart at 5–15N



Surgeons were asked to pull on a selection of Galaxy II Surgical 5mm and 12mm stays with force representative of tension they usually applied when retracting tissue during vaginal procedures


Stay hooks were attached to a gauge meter and both hook end and tension reading were blinded to the surgeon.

What we found

Readings of tension applied to stays representative of typical surgical use ranged from 2.5N –7.5N.

GALAXY II

Summary

Together, these investigations demonstrate that Galaxy II Surgical stays can safely sustain a maximum force of up to 3 times the usual tension applied during surgical procedures, without visible changes in hook or product design.

GALAXY II

Distributed by JUNE Medical contact@junemedical.com

United Kingdom and INTERNATIONAL:
INNOV8, Queen Alexandra Road, High Wycombe, HP11 2GZ,
Buckinghamshire, United Kingdom
+44 (0) 1628 330010

United States of America
257 Old Churchmans Rd., New Castle, DE 19720, USA
(302) 408 0084

EC REP **Sweden** (EC REP)
Alsbergsvagen 10, 51156 Kinna, Sweden

Manufactured by Mosaic Surgical Limited
Innov8 - Queen Alexandra Road High Wycombe,
Buckinghamshire HP11 2 GZ, United Kingdom
contact@mosaicsurgical.com

MSM007 Rev 1 Last Reviewed Sept 2020. Always read the IFU. © MOSAIC SURGICAL All rights reserved.