PuraBond™



Key Studies

Ear, Nose & Throat

3-D MATRIX
MEDICAL TECHNOLOGY

WELCOME

This document acts as a library of key studies which showcase PuraBond's varied uses across the field of Ear, Nose and Throat (ENT) and Head & Neck.

For **all** publications and clinical data on PuraBond for ENT, visit our website: **3dmatrix.com/clinical-studies/**
If you'd like more information on PuraBond or additional details on how the product may be used in a particular procedure, don't hesitate to reach out to us at: **infoeu@puramatrix.com**

Please note: any publications that feature an asterisk (*) at the end of their title indicate that there is reference(s) to off-label uses of the PuraBond product. For all approved indications, please read the Instructions for Use [1].

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NASAL ENDOSCOPIC SURGERY

A novel haemostatic agent based on self-assembling peptides in the setting of nasal endoscopic surgery, a case series

MF. Lee, Z. Ma, A. Ananda

Aim: To evaluate the efficacy and suitability of RADA16 [PuraBond] in functional endoscopic sinus surgery (FESS) procedures.
Summary: 60 patients with severe allergic rhinitis and intractable nasal obstruction resistant to medical treatment underwent endoscopic powered turbinoplasty using RADA16 as a haemostatic adjunct.
Conclusions: No re-bleeding noted in routine 4 week postoperative follow-up. Visual (nasal endoscope) inspection showed normal healing in absence of any adhesion formation in all the patients. Application technique has a low difficulty learning curve with effective application usually achieved on the first use.

AUS, 2017

Use of RADA16 [PuraBond], a novel haemostatic matrix based on self-assembling peptides in the prevention of nasopharyngeal adhesion formation

E. Wong, J. Ho, M. Smith, N. Sritharan, F. Riffat, M.C. Smith

Aim: A case study to show the successful application of RADA16 [PuraBond] following division of a nasopharyngeal/palatal stenosis following radiotherapy.
Summary: The patient developed severe nasopharyngeal stenosis following concurrent chemoradiotherapy. Topical application of 4 mL RADA16 onto the newly exposed surfaces following division of a nasopharyngeal/palatal stenosis. Follow-up at 2 months.
Conclusions: The patient experienced resolution of symptoms and no evidence of re-adhesion. Effective use of a combination of coblation and PuraBond.

AUS, 2020

RADA16, a self-assembling peptide (SAP) for haemostasis in nasal endoscopic surgery, a case series in Australia

D. Soodin, S. et al.

Aim: To assess the clinical performance in haemostasis and safety of RADA16 2.5 % [PuraBond] in patients undergoing endoscopic endonasal surgery in Australia.
Summary: N=167. 148 turbinate reductions ± septoplasty ± FESS, 19 FESS without turbinate reduction. A mean dose of 3.12 mL (total for both sides of the nose) RADA16 was used.
Conclusions: RADA16 proved easy to use and effective in achieving haemostasis (98.2 %) in a wide variety of surgical scenarios in endonasal surgery with reduced adhesion formation. RADA16, mainly used in place of nasal packing and minimal diathermy, resulted in a low incidence of adhesions requiring additional treatment (4.2 %) with minimal crusting.

AUS, 2022

CERVICAL ENDOCRINE SURGERY

The use of self-assembling peptides [PuraBond] for hemostasis in cervical endocrine surgery. A real-life case series of 353 patients

Y. Gangner, M. Bagot d'Arc, C. Delin

Aim: To assess the performance and safety of RADA16 [PuraBond] to achieve haemostasis in cervical endocrine surgery.
Summary: N=353 underwent thyroidectomy and/or parathyroidectomy using RADA16 at the end of surgery in contact with recurrent nerves and parathyroid glands. 3 mL of RADA16 was applied in a thin layer to the oozing tissue. RADA16 was used without drainage in 115 procedures (32.21 %). Follow-up visit performed on average 6.16 weeks after surgery.
Conclusions: RADA16 is easy to use and effective for haemostasis in open cervical endocrine surgery, with less than 1 % of postoperative bleeding. No damage to the surrounding structures was seen.

FR, 2022

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TRANS-ORAL ROBOTIC SURGERY (TORS)

UK, 2023

Comparison between RADA16 [PuraBond] and SurgiFlo® as haemostatic agents used in oncologic Transoral Robotic Surgery (TORS)

B. Sahota, M. Khan, B. Jeong, A. Takhar, J.C. Hodge, S. Krishnan, A. Foreman

Aim: To compare postoperative haemorrhage rates when RADA16 and SurgiFlo are used during TORS.
Summary: Prospective, non-randomised, observational study on consecutive patients undergoing oncological TORS resections. N=71; 57.71 % of patients underwent lateral oropharyngectomy, 38.57 % underwent tongue base resection, and the remaining 4.29 % underwent other procedures. RADA16 and SurgiFlo were used in 30.99 % and 67.60 % of cases respectively.
Conclusions: The overall rate of postoperative haemorrhage was 5.63 %, and showed no significant difference between SurgiFlo and RADA16 (4.17 %, 4.55 %, p=0.94). The return to theatre rate was 2.81 %, both cases were T4 tumour resections. There was no treatment related 30-day mortality.

Utilisation of RADA16 [PuraBond] in Trans-Oral Robotic Surgery (TORS) for Oropharyngeal Cancer

KK. Gupta, G. Garas, M. Idle, S. Germain, M. De

Aim: To evaluate the efficacy and safety of RADA16 [PuraBond] in TORS.
Summary: N=37. Patients with oropharyngeal cancer underwent TORS using RADA16 as a haemostatic agent. Postoperative haemorrage (24h): 0 %, postoperative haemorrage (1-30 days): 0 %, requirement of feeding tube or tracheostomy: 0 %, hospital readmission: 0 %.
Conclusions: This study demonstrates a potential role for PuraBond in TORS due to promising outcomes (bleeding, swallowing, pain and length of hospital stay).

UK, 2022

UK, 2025

The effect of PuraBond on post-operative pain following transoral resections of primary oral or oropharyngeal mucosal lesions: A randomised controlled study

J. Fleming, R.G. Asswad

Aim: To evaluate the effect of PuraBond [RADA16] in post-operative pain following transoral resection of oral/oropharyngeal lesions.
Summary: A prospective, blinded, single-centre randomised control trial (RCT), comparing PuraBond with no topical agent. N=68 (PuraBond n=32, control n=36). Post-op pain scores were evaluated with a visual analogue scale for 30-days. Mean pain score was 2.56 (PuraBond) and 3.41 (control). The PuraBond group had significantly less increase in pain from pre-operative baseline (0.61, 95%CI 0.12-1.10, p=0.016), and significantly fewer patients in the PuraBond group consumed any opioid analgesia in the first 24 h postoperatively (34.4%) compared to the control group (58.3%, p =0.048). Finally, post-operative haemorrhages were three times higher in the control group (6.3% [PuraBond] vs 16.7% [control]; p=0.266).
Conclusions: PuraBond for head and neck resections is a safe and potentially useful surgical adjunct to reduce post-operative pain. Further studies required to examine post-operative haemorrhage trends.

ADULT TONSILLECTOMY

Intra-Operative RADA16 Haemostats: A Comparative Trial in Adult Tonsillectomy

J. Michael, N. Patel, A. Kaleva, L. Bateman, O. Wakelam, J. Stephens

Aim: To evaluate the efficacy (postoperative bleeding) of PuraBond compared to no treatment.
Summary: A single-centre, retrospective comparative study. N=164 adult tonsillectomy cases were analysed and compared with a trial study (N=21). RADA16 was applied at the end of surgery to the tonsillectomy wound bed. Readmission rates for postoperative bleeding were 3-fold lower in RADA16 group when compared to the control (4.8% vs. 14.6%). Two control subjects (1.2%) required re-operation for recalcitrant bleeding; no RADA16 subjects (0.0%) required re-operation for any reason.
Conclusions: The study showed a reduced need for surgical intervention and a significantly reduced readmission rate (3 times) for post op. bleeding with intraoperative PuraBond use. High scores for ease-of use, haemostatic efficacy and the benefits of the gel's transparent nature.

UK, 2024

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ORDERING INFORMATION

Product Order Codes:

PuraBond 1mL:	621-204	621-210	621-216
PuraBond 3mL:	621-205	621-211	621-217
PuraBond 5mL:	621-206	621-212	621-218

Locate your local distributor:
https://3dmatrix.com/our-suppliers-and-distributors

Accompanying applicators are also available. Find more information here: https://3dmatrix.com/products/accessories

INDICATIONS FOR USE

PuraBond is indicated for haemostasis in the following situations encountered during surgery or endoscopic procedure, when haemostasis by ligation or standard means is insufficient or impractical[1]:

- Bleeding from small blood vessels and oozing from capillaries of the parenchyma and surrounding tissues of solid organs
- Oozing from vascular anastomoses to native or artificial vessels, on the surface of blood vessels and surrounding tissues

PuraBond also allows:

- A clear view of the bleeding site
- The fully synthetic peptide solution to be inert and safe to use.
- 95% effectiveness in sustaining haemostasis without additional treatment in the first 24 hours following ENT procedure.

(1) PuraBond IFU-009 Rev2, PuraBond IFU-014 Rev2, PuraBond IFU-020 Rev1



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Further clinical studies available:
www.3dmatrix.com/clinical-studies

Please note:
These publications contain data which are currently not within PuraBond indications.

- They concerns within, the prevention of secondary haemorrhage (within 1-30 days after surgery) and the treatment of postoperative pain which is not covered by the current indication of PuraBond.

3-D MATRIX
MEDICAL TECHNOLOGY

3-D Matrix Europe SAS
11 chemin des Petites Brosses
69300 Caluire-et-Cuire-FRANCE
Tel: +33 (0)4 27 19 03 40
infoeu@puramatrix.com
www.3dmatrix.com

CH REP QUNIQUE GmbH
Bahnhofweg 17,
5610 Wohlen
CHRN-AR-20000058

PuraBond is a class III medical device, CE marked according to Medical Devices Regulation (EU) 2017/745

CE 2797 BSI

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