

Technical update on PPH Technologies:

High quality, affordable NASG; balloon Tamponade; and
haemostatic Agents

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Drivers of affordability and quality initiatives

- High cost of the original NASG
- Additional costs incurred through logistics inefficiencies
- Quality issues



Photo credit: Suellen Miller



Process toward affordable, quality NASG

- Fingerprint mapping
- DMR (Device Master Record)
- Sourcing
- Quality plan
- Ordering



Process (finger print mapping)

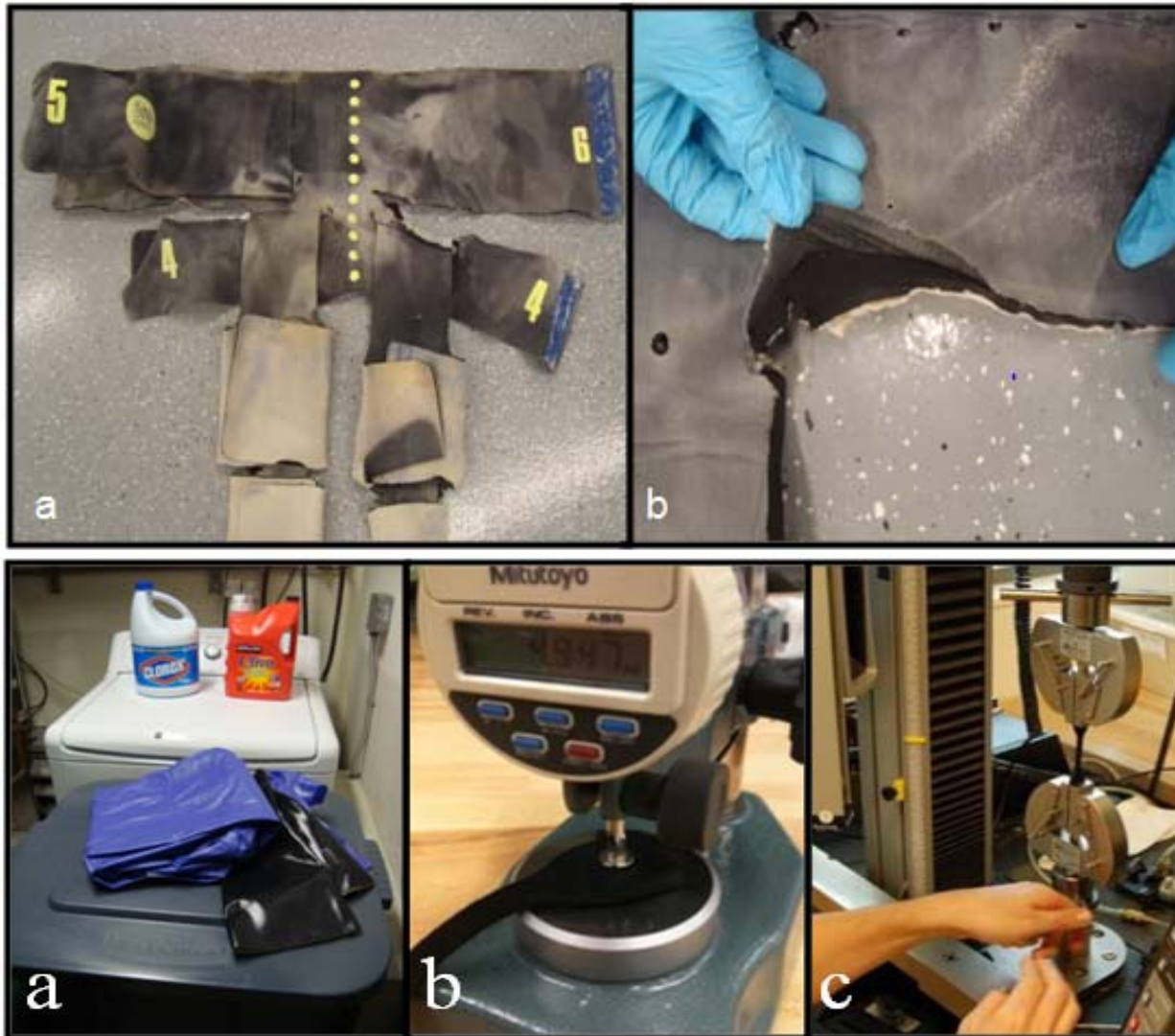


Photo collage credit: A. Beddoe, PATH

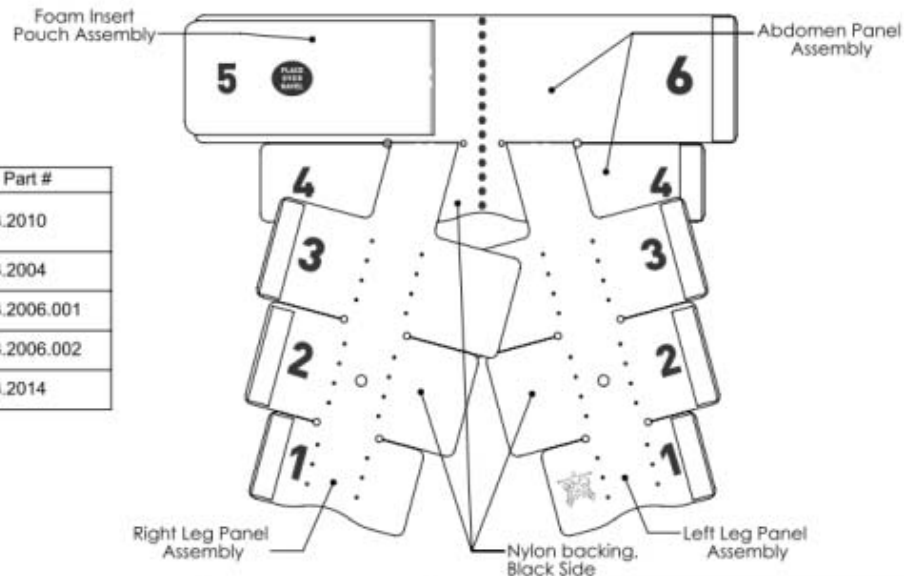


Process (DMR)

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REVISION	DCO NUMBER	DESCRIPTION	DATE	INITIAL
A	04.73.3002	INITIAL RELEASE	06/22/10	AGB
B	04.73.3003	UPDATED TOLERANCE & ADDED FRI POINTS	10/15/10	AGB
C				
D				

INSIDE SURFACE OF NASG SHOWN WITH GRAPHICS



Quantity	Description	Part #
1	FoamPad and Ball Pouch Assembly, Large	04.73.2010
1	Abdomen Panel Assembly, Large	04.73.2004
1	Right Leg Assembly, Large	04.73.2006.001
1	Left Leg Assembly, Large	04.73.2006.002
1	Carrying Strap Assembly	04.73.2014

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE GIVEN IN INCHES
[ALTERNATE UNITS] ARE MILLIMETERS

LINEAR TOLERANCE:		ANGLE TOLERANCE:	
INCH	MM	DEGREES	
$X = \pm .5$	$[X] = \pm [12.7]$	$\pm 0.5^\circ$	
$XX = \pm .375$	$[X] = \pm [9.5]$		
$XXX = \pm .125$	$[XX] = \pm [3.175]$		
$XXXX = \pm .0625$	$[XXX] = \pm [1.5875]$		

MATERIAL	Silkscreen
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FINISH

CAD FILE
04.79.38221: 8 (toASG-Fuß Assembly, LARGES)

DRAWN BY **AGR**

SIGNATURE _____

TECH. COORD

SIGNATURE _____

TEAM LEAD

SIGNATURE _____

DO NOT SCALE DRAWING

INTERPRET DRAWING PER ASME Y14.5M-1994

CAD MAINTAINED DRAWING. CHANGES TO PART / ASSEMBLY GEOMETRY MUST BE INCORPORATED INTO PART / ASSEMBLY CAD. PERMANENT MANUAL ALTERATION NOT PERMITTED.

DATE 4/22/08

0/22/00

DATE 10/15/01

10/15/11

DATE _____

10/15/1

path

Program for Appropriate Technology in Health

TITLE NASG Graphic Locations
LARGE

姓名: _____

A

DOCUMENT NO.

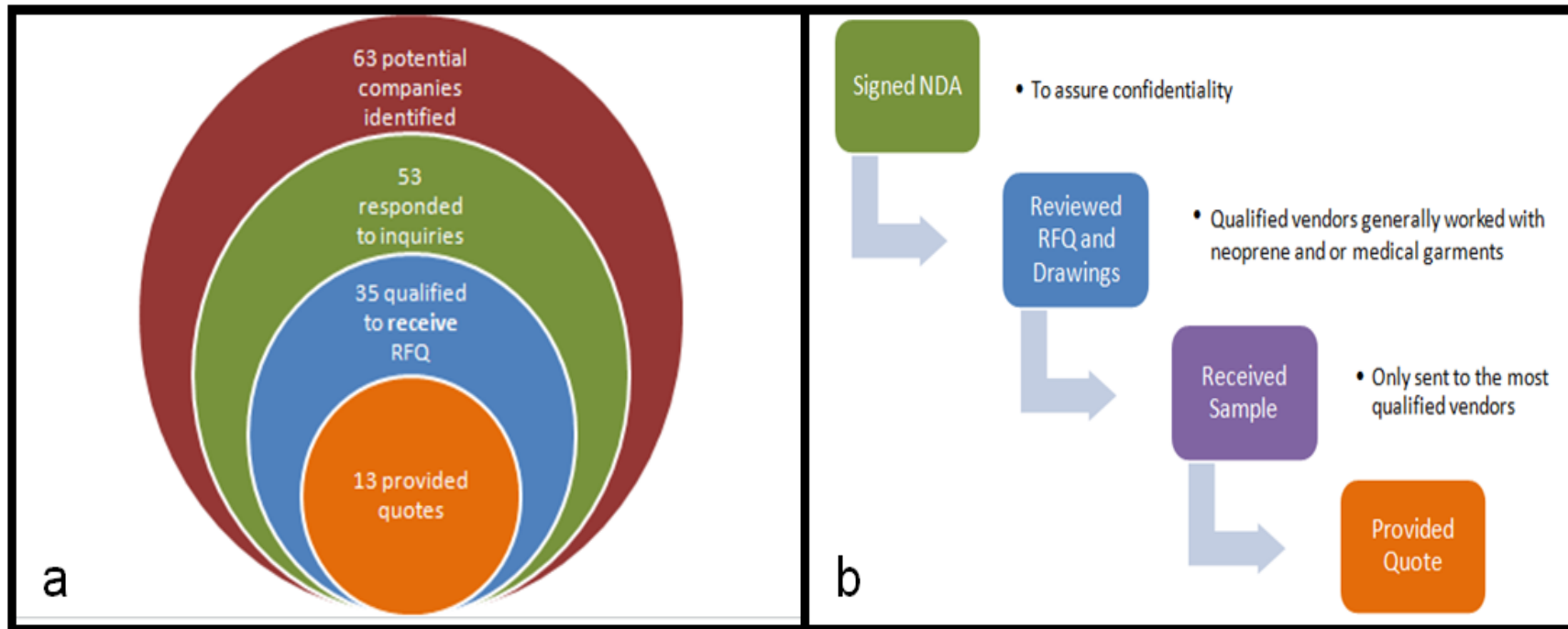
04.73

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Process (sourcing)

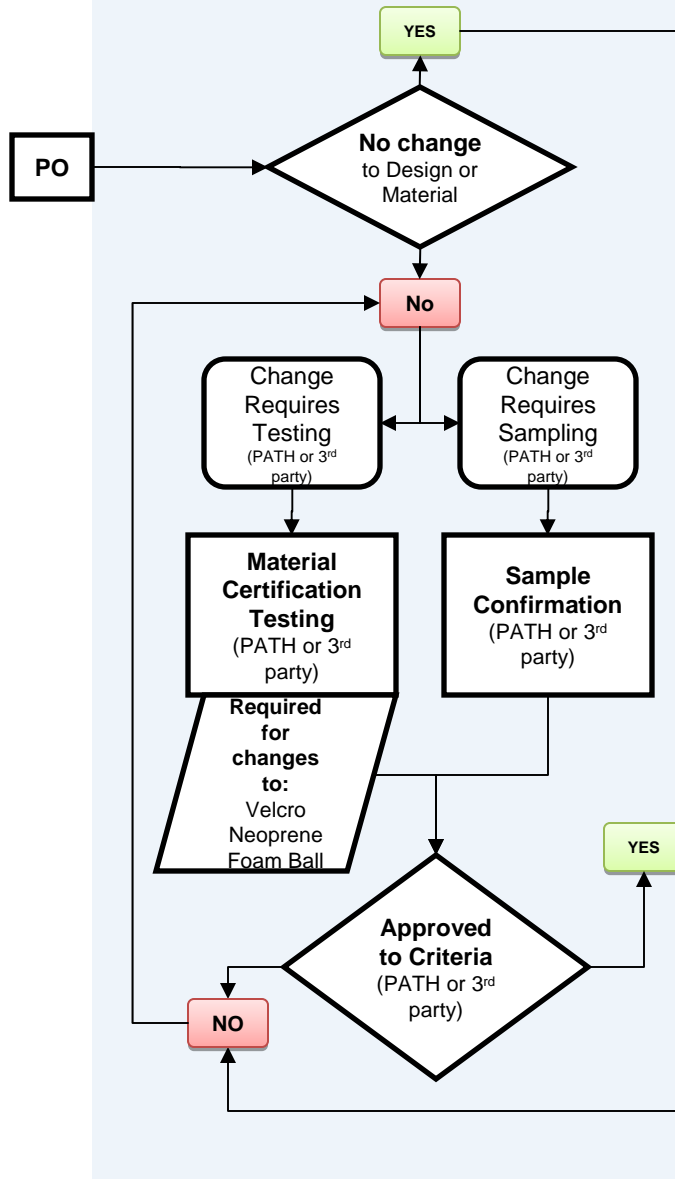


Process (Quality Plan)

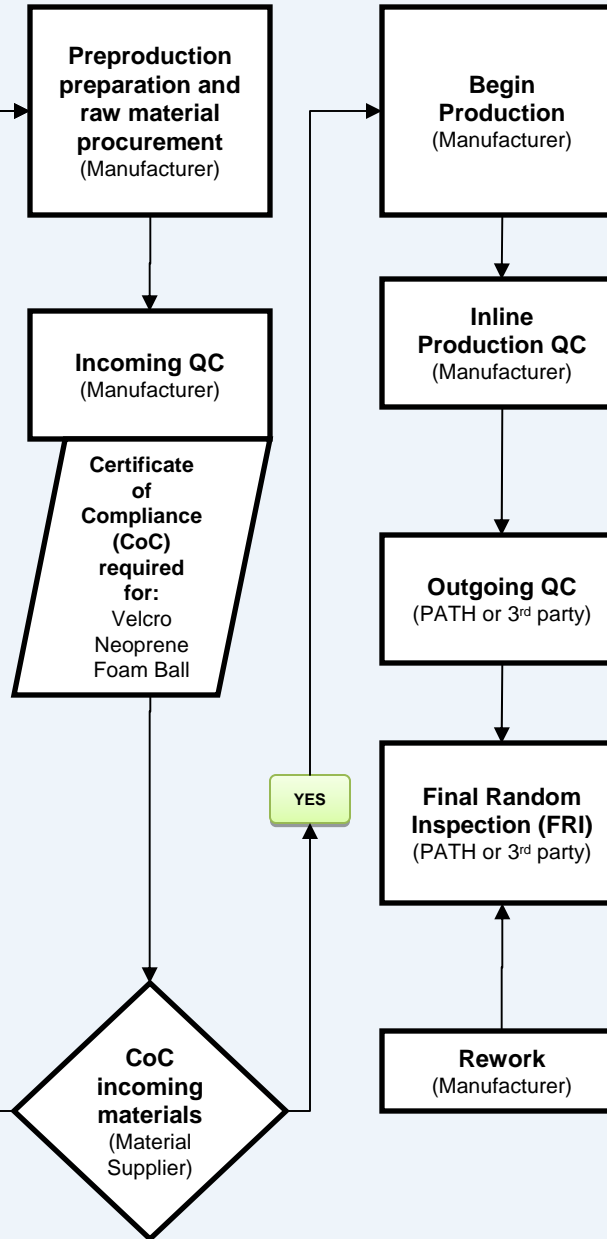
- Ensures high quality of samples is carried out through production
- Development of the QP includes risk assessment, understanding supplier motives
- Qualified materials
- Final Inspection (3rd party) prior to shipment



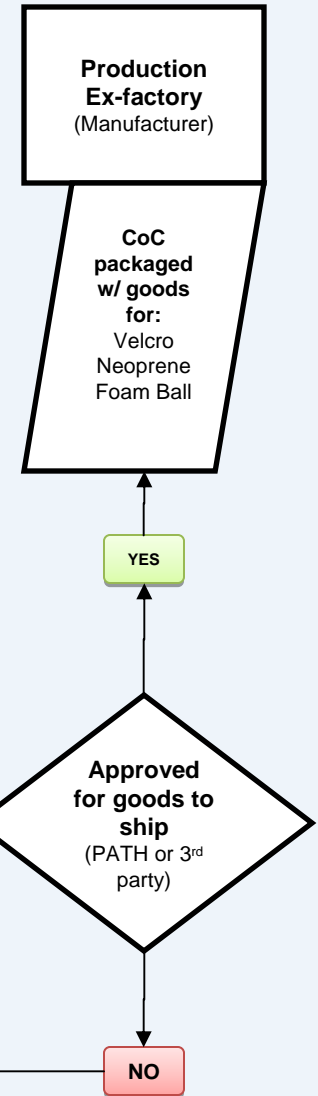
Design and Material Control



Manufacturing



Order Fulfillment



Results

- Fully qualified large NASG manufacturer in China who can supply the garment at a price of US\$54 (freight on board [FOB]).
- Technology transfer completed to a large NASG manufacturer in India who can supply the garment at a price of US\$65 (FOB). Qualification of this manufacturer is still in progress.





Remaining challenges

- Vissco – Indian supplier
- Multiple Sizes
- Demand, minimum order quantities and lead times
- Cleaning logistics and protocol



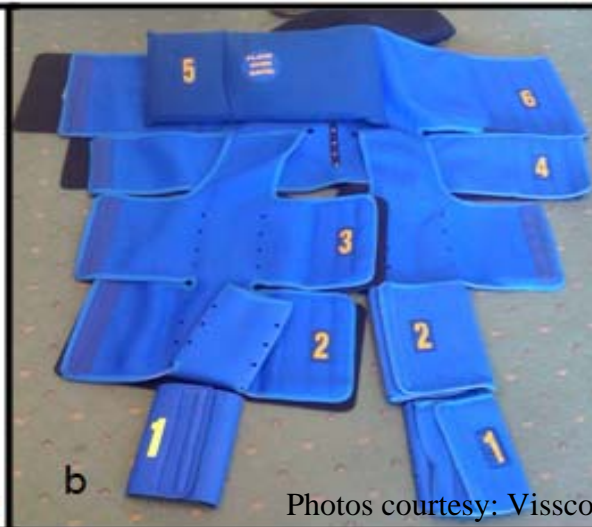
Visasco



Photo credit: A. Beddoe



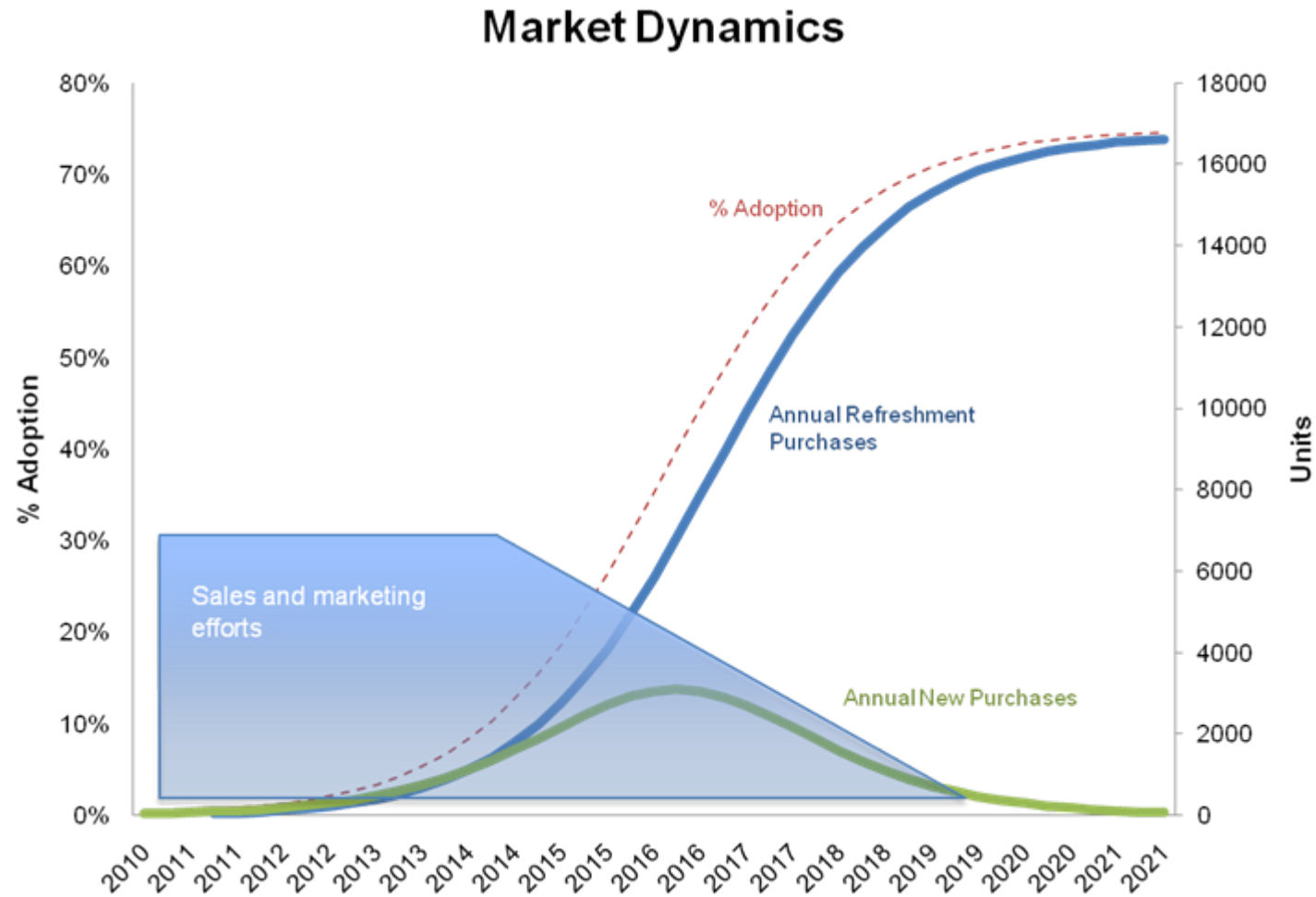
Photo credit: A. Beddoe



Photos courtesy: Visasco



Demand, minimum order, lead times



NASG Sizes

	CURRENT	RECENT HISTORY	ANCIENT HISTORY
LARGE	standard geometry but with 4-5" added to panels 5 and 6	standard geometry but with 4-5" added to panels 5/6	standard geometry but with 4-5" added to panels 5 and 6
MEDIUM	standard geometry	standard geometry	standard geometry
SMALL	small geometry designed for India	N/A	N/A



Cleaning logistics and protocol



Photo courtesy: Pathfinder



Other emerging PPH technologies

- Balloon tamponade
- Hemostatic agents





Photo credit: P. LaBarre



Photo credit: P. LaBarre

Hemostatic agents

- **Haemostatic agents:** have gained widespread use for pelvic surgery in last few years. Specifically, they are good for use in areas of difficult accessibility. (Shah, 2009)
- **Uterine Atony:** “FlowSeal delivered to the oozing area through single syringe, Hemostasis was achieved instantaneously – recommended as an adjunct to conventional methods” (Moriarity, 2007)
- **Challenges with mixing/packaging:** Further research needs to be conducted to improve product use. Current challenges include ease of mixing, form factor not specifically designed for uterine application, delivery method, pre-measured dose packaging.
- **Price negotiations**



Large NASG ordering details

Price: \$53.76 USD FOB China

Lead time: 60 days

Minimum order: 1000 units

Manufacturer: Neil Pryde Performance Manufacturing, China

Orders placed to: Blue Fuzion Group Ltd- Hong Kong

<http://www.bluefuziongroup.com/>

Contact: julian.cosgrave@bfgroup.asia

Questions: contact Paul LaBarre, PATH; plabarre@path.org



NASG Team Acknowledgments

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